UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The Muscogee (Creek) Nation v. Purdue Pharma L.P., et al.* Case No. 18-op-45459 *The Blackfeet Tribe of the Blackfeet Indian Reservation v. AmerisourceBergen Drug Corp., et al.* Case No. 18-op-45749	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MEMORANDUM OF LAW IN SUPPORT OF THE MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS THE TRIBES' FIRST AMENDED COMPLAINTS

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INTRODUCTION

Plaintiffs are two Indian tribes (the "Tribes") seeking to hold liable numerous companies that manufacture and sell FDA-approved prescription opioid medications (the "Manufacturers").[1] The essence of their cases is that the Manufacturers are responsible for all harms associated with the nationwide crisis of opioid addiction and abuse. They want this Court and a civil jury not only to declare and enforce new legal standards for marketing prescription opioids, but also to require the Manufacturers to pay all costs associated with providing public services in connection with illicit opioid abuse. But the opioid crisis cannot and should not be fixed through the tort system. Although the Tribes attempt to shoehorn their claims into a tort suit, it just doesn't fit. Their claims are legally baseless and should be dismissed.

The Tribes make their claims even though the opioid medications in question have been approved by the Food and Drug Administration (FDA) for the treatment of long-term, chronic pain; the FDA-approved labeling fully discloses the risks of the medicines; and the Manufacturers operate within a highly regulated framework designed, among other things, to prevent diversion. The Tribes' claims fail in their entirety for a multitude of independent reasons.

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[1] "Manufacturers" refers to Purdue Pharma LP, Purdue Pharma Inc., and The Purdue Frederick Company Inc. ("Purdue"); Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. ("Allergan/Actavis"); Watson Laboratories, Inc.; Actavis Pharma, Inc.; Actavis LLC; Teva Pharmaceuticals, USA, Inc. and Cephalon, Inc. ("Teva"); Johnson & Johnson ("J&J") and Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. ("Janssen"); Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. ("Endo"); Insys Therapeutics, Inc. ("Insys"); and Mallinckrodt LLC and SpecGX LLC ("Mallinckrodt"). Not all Manufacturers, however, are named in both Tribe cases: the Blackfeet First Amended Complaint ("Blackfeet 1AC") names them all, while the Muscogee First Amended Complaint ("Muscogee 1AC") names only certain of the Purdue, Allergan/Actavis, Endo, and Teva entities. Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc do not join this motion because they are an Israeli corporation, Irish holding company, and Irish company, respectively, that have not been served and over which no personal jurisdiction exists.

First, the Tribes' claims all seek to recover costs stemming from the misuse and abuse of prescription opioids and illicit opioids by downstream actors who are far outside the Manufacturers' control and who in many instances engaged in criminal conduct. Tort law does not permit recovery for damages that are so remote and attenuated from a defendant's alleged misconduct. Indeed, courts have repeatedly held that even tobacco companies, whose products provide *no* medical benefits to individuals or society, are not liable for increased aggregate healthcare costs.

Second, the Tribes seek to recover for harms that cannot be redressed through litigation, and they invoke a host of statutes that are not intended to protect the Tribes from the sorts of harms they allege. The Tribes' healthcare costs, for example, are paid by the federal government. And the RICO Act protects against *commercial* injuries, not injuries an Indian tribe suffers as a sovereign or provider of public services. The Tribes' complaints are replete with similar flaws.

Third, the Tribes invoke public nuisance and unjust enrichment, but neither claim is intended to cover the alleged misconduct. No Oklahoma or Montana decisions have embraced their use in the manner the Tribes seek here, and this Court should not be the first.

Fourth, the Tribes cannot employ tort law to second-guess the considered judgments of the FDA. Congress has assigned to the FDA the responsibility of determining whether and how opioids can be used and marketed. The FDA has considered and expressly rejected proposals that would have (i) prohibited doctors from prescribing opioid medications for long-term pain management, and (ii) imposed maximum daily dosage limits. In making those choices, the FDA emphasized that such restrictions are "not support[ed]" and "not supportable" under the "scientific literature" cited by the strongest critics of opioids. Letter from FDA to Physicians for Responsible

Opioid Prescribing (PROP) at 12, 14 (Sept. 10, 2013) ("FDA Response").[2] Because the Tribes' state-law claims seek to impose liability for conduct the FDA has expressly authorized, federal law preempts those claims.

Fifth, the Tribes have failed to comply with basic procedural rules that govern tort litigation. Although the Tribes charge the Manufacturers with fraud on a massive scale, the Tribes fail to make such allegations with the particularity demanded by Federal Rule of Civil Procedure 9(b). They do not identify even a single false or misleading statement made to a single prescriber in Montana or Oklahoma—much less one that caused the prescriber to write a medically inappropriate opioid prescription that harmed the Tribes. Their pleadings do demonstrate, however, that the vast majority of their claims are barred by the relevant statutes of limitation.

Because the legal theories underlying the Tribes' complaints are baseless, the complaints should be dismissed now.[3]

ARGUMENT

In recent decades, tort suits (similar to the Tribes') seeking society-wide remedies have been brought against the producers of a variety of legal products. Those lawsuits have largely failed, and rightly so. *See, e.g.*, *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415 (3d Cir. 2002) (firearms); *Native Village of Kivalina v. ExxonMobil Corp.*, 696 F.3d 849 (9th Cir. 2012) (fossil fuels); *State ex rel. Miller v. Philip Morris Inc.*, 577 N.W.2d 401 (Iowa 1998) (tobacco); *State v. Lead Indus. Ass'n*, 951 A.2d 428 (R.I. 2008) (lead paint); *Ashley Cty. v. Pfizer, Inc.*, 552 F.3d 659 (8th Cir. 2009) (cold medicine).

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[2] The FDA Response is attached to the Morris Declaration as Exhibit A. It is cited and quoted by both Tribes' complaints. *See* Muscogee 1AC ¶ 113 & n.32; Blackfeet 1AC ¶ 255 & n.85.

[3] Unless otherwise indicated, this Memorandum omits from quotations all internal citations, alterations, and quotation marks.

Although the precise doctrinal bases for these decisions have varied, they all spring from a common underlying principle: The judicial system is not equipped to solve complex, multi-faceted societal ills. As one federal judge recently put it, some "problem[s] deserve[] a solution on a more vast scale than can be supplied by a district judge or jury." *City of Oakland v. BP P.L.C.*, No. 17-CV-6011, 2018 WL 3109726, at *9 (N.D. Cal. June 25, 2018). That insight applies here. The Tribes' claims fail on multiple, overlapping grounds.[4]

I. FUNDAMENTAL TORT PRINCIPLES FORECLOSE THE TRIBES FROM RECOVERING FOR REMOTE AND INDIRECT HARMS

The Tribes seek to hold the Manufacturers liable for an enormous range of harms that are, as a matter of law, too far removed from the Manufacturers' alleged misconduct to form the basis for liability. All of the Tribes' claims should be dismissed for failing to plead proximate cause, and the negligence claims should be dismissed for the additional reason that the Manufacturers have no duty to prevent those alleged harms.

A. All Of The Tribes' Claims Against The Manufacturers Fail To Plead Proximate Causation

The Tribes allege that the Manufacturers committed two forms of misconduct: (1) some Manufacturers engaged in deceptive marketing, falsely overstating the benefits and understating the risks of their prescription opioid medicines to doctors and patients (*see* Muscogee 1AC ¶¶ 102-56; Blackfeet 1AC ¶¶ 144-468); and (2) they failed to properly control the distribution of their medicines by not identifying, reporting, and taking steps to halt suspicious orders (*see* Muscogee 1AC ¶¶ 329-52; Blackfeet 1AC ¶¶ 474-585). The Tribes were not directly impacted by this purported misconduct. Instead, the Tribes assert that they were harmed in various indirect ways.

[4] For the Court's convenience, Addendum A to this Memorandum contains charts summarizing the grounds of dismissal applicable to each of the counts in the Tribes' complaints.

For their first theory of liability, the alleged chain from conduct to injury is as follows: (i) those Manufacturers who engage in promotion made deceptive claims about their opioids (**the conduct**); (ii) some physicians were exposed to the Manufacturers' claims; (iii) those claims caused some of those physicians to prescribe opioids they otherwise would not have prescribed and that are medically inappropriate; (iii) which caused some of their patients to decide to take opioids; (iv) which caused some of those individuals to become addicted; (v) which caused some of those individuals to incur additional medical costs, neglect or abuse their families, lose their jobs, or commit crimes; (vi) which caused the Tribes to expend additional resources on medical treatment, emergency services, social welfare programs, and criminal justice (**the injury**).

The second theory of liability follows a similarly attenuated path: (i) the Manufacturers failed to identify and report suspicious orders (**the conduct**); (ii) distributors, which have their own independent monitoring and reporting obligations, also failed to identify and report suspicious orders; (iii) the suspicious orders, had they been identified and reported to the Drug Enforcement Administration (DEA), would have been deemed improper and stopped by the DEA; (iv) the order that would have been stopped were then either criminally diverted or used to fill improper prescriptions; (v) individuals—some legally, some illegally—used opioids originating from these suspicious orders; (vi) the use or abuse of these opioids caused some of these individuals to incur medical costs, neglect or abuse their families, lose their jobs, or commit crimes; (vii) which caused the Tribes to expend additional resources on medical treatment, emergency services, social welfare programs, and criminal justice (**the injury**).

As these tortured chains of causation reveal, the Tribes' alleged injuries are far removed from the wrongful conduct alleged; they are only derivative of injuries suffered by individuals earlier in the chain of causation; and the causal chain is broken by the independent intervening acts

of doctors, pharmacists, distributors, and (in many instances) criminal actors. Thus, the Tribes' own allegations, accepted as true, establish that their injuries were not proximately caused by the Manufacturers' conduct. All of the Tribes' claims should be dismissed for this reason alone. *See also Summit* MTD §§ II.B.2, III.B.2 (advancing similar arguments).

1. The Tribes' Injuries Were Not Proximately Caused By The Manufacturers' Conduct Because They Are Indirect, Derivative, And Remote

The concept of proximate cause in tort law "is shorthand for the policy-based judgment that not all factual causes contributing to an injury should be legally cognizable causes." *CSX Transp., Inc. v. McBride*, 564 U.S. 685, 701 (2011). As the Supreme Court has explained, the common law requirement of proximate cause precludes tort liability where there is no "direct relation between the injury asserted and the injurious conduct alleged." *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992). Instead, the "general tendency of the law . . . is not to go beyond the first step." *Id.* at 271. Accordingly, under common law principles, a plaintiff whose "harm flow[s] merely from the misfortunes visited upon a third person by the defendant's acts" is considered "to stand at too remote a distance to recover." *Id.* at 268-69; *see Perry v. Am. Tobacco Co.*, 324 F.3d 845, 848 (6th Cir. 2003) (when a plaintiff's injuries "are purely contingent on harm to [third parties], these injuries are clearly indirect" and thus "too remote" to satisfy tort law's proximate cause requirement).

Yet that is precisely where the Tribes stand. To be sure, the Tribes repeatedly assert that the Manufacturers have "directly" injured them (*e.g.*, Muscogee 1AC ¶¶ 352, 430; Blackfeet 1AC ¶¶ 34, 850), but that is a mere legal conclusion. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009) (court will not accept legal conclusions as true on a motion to dismiss). The various types of harms and expenses the Tribes assert all flow from the fact that individual members of the Tribes have allegedly suffered underlying injuries—either as a result of their own opioid use or through the

criminal or tortious actions of others abusing opioids. Because the harm to the Tribes is "inherently contingent" on harm inflicted on others (*Perry*, 324 F.3d at 849), the Tribes' damages are too remote to have been proximately caused by the Manufacturers' conduct.

That conclusion is further bolstered by the Supreme Court's analysis in *Holmes*. There, the Court identified three reasons why proximate cause demands a sufficient degree of directness, and all three *Holmes* factors compel the conclusion that the Tribes' injuries here are too remote.

First, the Court explained that "the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors." *Holmes*, 503 U.S. at 269. Here, it is clear from the face of the complaints that the damages sought by the Tribes are both highly speculative and difficult (if not impossible) to calculate given the many other potential causes of their alleged injuries. The Tribes have to demonstrate, for example, which doctors prescribed opioids as a result of the Manufacturers' misrepresentations as opposed to some other reason. Even more problematic, they have to prove which instances of crime, unemployment, family dysfunction, and the like would not have occurred but for the Manufacturers' alleged tortious conduct. Many courts have found that these sorts of "wickedly hard" damages questions signal the absence of proximate cause and justify dismissal on the pleadings. *E.g.*, *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Tr. Fund v. Philip Morris Inc.*, 196 F.3d 818, 825-26 (7th Cir. 1999).

For example, in suits seeking to hold cigarette and gun manufacturers liable for widespread societal harms, courts have noted the practical impossibility of isolating the role of the manufacturers' allegedly tortious conduct from the myriad other causes of the alleged harms. *See, e.g.*, *Philadelphia*, 277 F.3d at 425 ("Additionally, plaintiffs' damages are speculative as it would be difficult to calculate how many incidents could have been avoided had the gun manufacturers

adopted different policies."); *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 239-40 (2d Cir. 1999) (noting that it would be "virtually impossible for plaintiffs to prove with any certainty" how many smokers would have stopped smoking in the absence of tobacco companies' fraud). The Tribes' suits suffer from the same intractable problems.

Second, the *Holmes* Court noted that "recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries." *Holmes*, 503 U.S. at 269. Here, the Court would face an impossible task in trying to apportion alleged damages among the classes of plaintiffs and potential plaintiffs—including opioid users and the various public and private entities that purportedly bore the costs of widespread abuse, misuse, and addiction—in such a way as to avoid duplicative recovery.

And, *third*, the Court in *Holmes* recognized that "the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law" through suits of their own. 503 U.S. at 269. Individuals who have been directly injured by the allegedly tortious conduct of pharmaceutical manufacturers—including makers of opioids—can and do sue them directly. *See, e.g.*, *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511 (11th Cir. 2007).

2. The Dismissal of Suits Against Tobacco Companies Confirms The Absence Of Proximate Causation Here

The Tribes' claims here are reminiscent of those brought against tobacco companies by a variety of organizational plaintiffs responsible for providing healthcare, including insurers, public hospitals, states, foreign governments, and Indian tribes. *See, e.g.*, *Perry*, 324 F.3d 845; *Ala. Coushatta Tribe v. Am. Tobacco Co.*, 46 F. App'x 225 (5th Cir. 2002); *Serv. Emps. Int'l Union Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068 (D.C. Cir. 2001) ("*SEIU Fund*");

Ass'n of Wash. Pub. Hosp. Dists. v. Philip Morris Inc., 241 F.3d 696 (9th Cir. 2001) ("*Hospital Districts*"); *Teamsters*, 196 F.3d 818; *Laborers Local 17*, 191 F.3d 229; *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912 (3d Cir. 1999); *State ex rel. Miller v. Philip Morris Inc.*, 577 N.W.2d 401 (Iowa 1998). The plaintiffs in those cases alleged—much like the Tribes do here—that the tobacco companies had engaged in a decades-long campaign of fraud designed to hide the dangerous and addictive nature of cigarettes, the result of which was that many individuals began or continued to smoke and suffered serious health consequences. The plaintiffs claimed—much like the Tribes do here—that they had been injured by this conduct because they were forced to spend more on their members' (or constituents') healthcare. And—much like the Tribes do here—they sought relief under RICO and state-law tort claims.

The courts in every one of these cases dismissed the claims on the pleadings. Each court held that the plaintiffs' injuries were, as a matter of law, too remote to satisfy the requirement of proximate cause. In the words of one court, "*all* of plaintiffs' claims rely on alleged injury to smokers—without any injury to smokers, plaintiffs would not have incurred the additional expenses in paying for the medical expenses of those smokers." *Oregon Laborers-Employers Health & Welfare Tr. Fund v. Philip Morris Inc.*, 185 F.3d 957, 963 (9th Cir. 1999). As various courts explained, the three *Holmes* factors demonstrated that the plaintiffs' injuries were insufficiently direct. It would be extraordinarily difficult "to determine the extent to which [the plaintiffs'] increased costs for smoking-related illnesses resulted from the tobacco companies' conspiracy to suppress health and safety information, as opposed to smokers' other health problems, smokers' independent (i.e., separate from the fraud and conspiracy) decisions to smoke, smokers' ignoring of health and safety warnings, etc." *Steamfitters*, 171 F.3d at 933. The same analysis applies to the Tribes' claims.

Especially apposite here is *Alabama Coushatta Tribe*. There, an Indian tribe sought to recover against tobacco companies under RICO and state tort causes of action. Faced with the avalanche of authority rejecting such claims on proximate cause grounds, the tribe "argue[d] that its sovereign status and the fact that the injuries were alleged to have been suffered by the [t]ribe itself, apart from its members," somehow changed the analysis. 46 F. App'x at 225; *see also* Brief of Appellant 10, *Ala. Coushatta Tribe*, 46 F. App'x 225 (5th Cir. 2002) (No. 01-41198), 2002 WL 32180513 ("It is the damage to the Tribe itself—the loss of its size and strength and the injury to its interest in the health and well-being of its people—for which the Tribe seeks redress."). The Fifth Circuit found this argument so clearly lacking in merit that it summarily rejected the tribe's appeal, affirming the district court's conclusion that the tribe's injuries were too remote. 46 F. App'x at 225.

Like the tobacco plaintiffs, the Tribes are proposing "precisely the type of indirect, massive and complex damage litigation that the Supreme Court sought to preclude" through its articulation of the proximate cause requirement. *Or. Laborers-Emp'rs Health & Welfare Tr. Fund v. Philip Morris, Inc.*, 17 F. Supp. 2d 1170, 1179 (D. Or. 1998), *aff'd*, 185 F.3d 957 (9th Cir. 1999). The "tortured path from the [Manufacturers'] alleged wrongdoing to the [Tribes'] increased expenditures demonstrates that [the Tribes'] claims are precisely the type of indirect claims that the proximate cause requirement is intended to weed out." *SEIU Fund*, 249 F.3d at 1071. This Court should follow the unanimous approach of the courts deciding these tobacco cases—including the Sixth Circuit—and dismiss the Tribes' complaints.

3. The Presence Of Doctors And Criminal Actors In The Causal Chain Independently Demonstrates The Absence Of Proximate Cause

Holmes and its tobacco-litigation progeny suffice to demonstrate that the Tribes' injuries are, as a matter of law, too remote from the Manufacturers' alleged misconduct. In fact the causal

chain is even more attenuated here because of the role that third parties necessarily play—and that further attenuation provides even more reason to dismiss the Tribes' claims. Unlike cigarettes, which smokers can lawfully purchase on their own, opioids are highly regulated and can be lawfully obtained by patients only with a doctor's prescription. That means that in every case where the use of opioids has ultimately resulted in some kind of harm to the Tribes, either (i) a doctor determined that the use of these FDA-approved products was medically appropriate, (ii) the opioids were obtained by the criminal acts of someone other than the Manufacturers, or (iii) both. The role of these other, independent actors breaks the causal chain and makes liability especially inappropriate.

a. ***Intervening Acts Of Prescribing Doctors Break The Causal Chain***

In numerous cases alleging harms arising from the use of prescription medications, courts have recognized that the necessary presence of a prescribing doctor is an additional link in the causal chain that can render the injury too remote from the alleged misconduct of the manufacturer as a matter of law. In *Ironworkers Local Union No. 68 v. AstraZeneca Pharmaceuticals LP*, for instance, plaintiffs brought RICO and state-law tort claims against the maker of an antipsychotic medication, claiming that the defendant had misrepresented its safety and efficacy. 585 F. Supp. 2d 1339, 1341 (M.D. Fla. 2008). The district court dismissed their claims, holding that the plaintiffs had failed to plausibly plead proximate cause because the "independent medical judgment" of prescribing physicians was a "key independent factor" separating the alleged misconduct from the injury. *Id.* at 1344; *see also, e.g.*, *United Food & Commercial Workers Cent. Pennsylvania & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (affirming dismissal and noting "doctors' decisions to prescribe" the drugs as one reason the "causal theory [was] too attenuated"); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales*

Practices & Prods. Liab. Litig., No. 3:09-CV-20071, 2010 WL 3119499, at *7 (S.D. Ill. Aug. 5, 2010) (similar).

Notably, this is true even where the plaintiffs allege that the defendants' tortious conduct was intended to deceive doctors about the dangers and benefits of the drug in question. *See, e.g.*, *Ironworkers*, 585 F. Supp. 2d at 1341-42; *In re Yasmin*, 2010 WL 3119499, at *7. The Seventh Circuit's recent decision in *Sidney Hillman Health Center of Rochester v. Abbott Laboratories*, 873 F.3d 574 (7th Cir. 2017), is instructive. There, welfare-benefit plans alleged that a manufacturer had improperly promoted a drug for uses for which it was not proved to be safe and that the plans were injured by having to reimburse the resulting prescriptions. *Id.* at 575. The Seventh Circuit held that the plaintiffs had failed to plausibly plead proximate cause, noting that the allegations of deceptive marketing could not erase the independent role of the prescribing doctors: "[S]ome physicians doubtless were proof against the campaign of disinformation. They may not have changed their prescribing practices at all, or they might have changed them but done so in response to information that Abbott did not influence." *Id.* at 577. "Disentangling the effects of the improper promotions from the many other influences on physicians' prescribing practices would be difficult," and the plaintiffs had not alleged that they had made any effort to do so, "leav[ing] a serious problem in showing plausible causation, which is required even at the complaint stage." *Id.*

The same logic applies here. Although the Tribes allege that the Manufacturers engaged in various efforts to deceive doctors about the risks and benefits of opioids, "some physicians doubtless were proof against the campaign of disinformation." *Id.* Indeed, that is especially likely here for several reasons. To start, as the Blackfeet Tribe itself alleges, opioids' medicinal properties *and* their "potential for abuse and addiction" "have been recognized for millennia."

Blackfeet 1AC ¶ 100. Moreover, the Manufacturers' opioids have at all times been accompanied by FDA-approved labels "contain[ing] prominent warnings" about the risks of "addiction, overdose, and even death." FDA Response at 2. It would therefore be particularly difficult to "[d]isentangl[e] the effects of the improper promotions from the many other influences on physicians' prescribing practices." *Sidney Hillman*, 873 F.3d at 577; *see also Holmes*, 503 U.S. at 269 (difficulty ascertaining role of independent factors indicates injury is too remote). That the Tribes have made no effort to disaggregate is fatal to their claims.

b. *Intervening Acts Of Criminal Actors Also Break The Causal Chain*

Many of the Tribes' claims also rest on intervening criminal conduct by third parties. Among other things, the Tribes assert that the Manufacturers should be liable for the costs that indirectly flow to the Tribes from:

- The operation of "pill mills," in which "rogue prescribers" intentionally write phony prescriptions for non-medical uses. Blackfeet 1AC ¶ 16.
- The use of opioids illegally taken *from pharmacies* by outright theft, the use of stolen, forged, or invalid prescriptions, or malfeasance by pharmacy employees. Muscogee 1AC ¶ 12; *see also id.* ¶¶ 245-56 (citing numerous instances of pharmacy misconduct); Blackfeet 1AC ¶¶ 606-35 (same).
- The intentional use of illicit drugs that the Manufacturers neither make nor promote, such as heroin and carfentanil. Blackfeet 1AC ¶¶ 19, 669.
- "[C]hild abuse," "elder abuse," "burglary," "property damage," "violence," "domestic violence," and "criminal behavior" connected in some (unspecified) way to the use of opioids. Muscogee 1AC ¶¶ 20-21, 294; Blackfeet 1AC ¶ 679.

The notion that the Manufacturers are liable for these acts of intentional wrongdoing by third parties, over whom the Manufacturers have no control, should be rejected as a matter of law.

The Eighth Circuit rejected similar claims in *Ashley County v. Pfizer, Inc.*, 552 F.3d 659 (8th Cir. 2009). There, twenty Arkansas counties sought to recover costs associated with the methamphetamine epidemic from drug manufacturers whose cold medicines were used by

criminals to make methamphetamine. *Id.* at 663. Much like the Tribes, these counties alleged that the manufacturers knew that their products were being misused and failed to take steps to stop it. *Id.* at 663-64. The Eighth Circuit dismissed the claims for lack of proximate cause, observing that the chain of causation from the manufacturers' alleged misconduct to the counties' increased expenditures was long and necessarily included the "criminal actions" of third parties. *Id.* at 668, 670-71. Relaxing proximate cause to permit such liability, the Eighth Circuit correctly concluded, would "open Pandora's box to [an] avalanche of actions" against the manufacturers of any product that "can be linked to other societal problems." *Id.* at 671.

A number of courts likewise dismissed lawsuits by cities seeking to hold firearms manufacturers liable for the collective costs of gun violence. There, too, the courts found the connection between alleged wrongdoing and municipal costs too attenuated to satisfy the proximate cause requirement. In rejecting one such lawsuit, the Third Circuit aptly summarized the extended causal chain: "First, the defendant manufacturers sell guns to licensees; second, the licensees sell the guns to dealers; third, the dealer sells it to a lawful purchaser acting as a straw buyer; fourth, the straw buyer transfers the weapon to a criminal or a youth; fifth, the transferee uses the gun to commit a crime, or the youth injures himself or a companion; and finally, demand on the City's or the organizational plaintiffs' resources is increased." *Philadelphia*, 277 F.3d at 423-24. The court further noted that "for each individual injury, independent factors obviously come into play, such as criminal conduct, drug or alcohol abuse, or other misconduct by the owner." *Id.* at 425. It would thus be purely "speculative" to try "to calculate how many incidents could have been avoided had the gun manufacturers adopted different policies." *Id.*; *see also City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1138 (Ill. 2004) (dismissing claims against gun manufacturer and rejecting idea that dealers' alleged misconduct "can be deemed a legal cause

of a nuisance that is the result of the aggregate of the criminal acts of many individuals over whom they have no control").

The rationale of *Ashley County*, *Philadelphia*, and *Chicago*—and other decisions dismissing similar claims on the pleadings, *see, e.g.*, *District of Columbia v. Beretta, U.S.A., Corp.*, 872 A.2d 633, 639-51 (D.C. 2005); *Ganim v. Smith & Wesson Corp.*, 780 A.2d 98, 118-130 (Conn. 2001)—is directly applicable here. Like the makers of ephedrine and firearms, the Manufacturers "are in the business of providing a lawful product that may be used in unlawful ways, causing injury or death." *City of Chicago*, 821 N.E.2d at 1137. Given the pervasive role criminal actors play in creating the aggregate harms the Tribes allege—and the Manufacturers' complete lack of control over those downstream actors—the Manufacturers' conduct cannot be deemed the legal cause of the Tribes' society-wide injuries.

4. Lack Of Proximate Causation Is Fatal To All Of The Tribes' Claims

Because their injuries are fundamentally indirect and derivative, and because multiple independent actors break the causal chain, the Tribes have failed to plausibly plead proximate causation. That failure is fatal to *all* of the Tribes' claims.

RICO: Proximate cause is an element of the Tribes' RICO claims. *See Holmes*, 503 U.S. at 265-68. Indeed, *Holmes* and the tobacco cases discussed above were RICO cases. The logic of their analysis applies directly to the RICO claims here.

Lanham Act: Proximate cause is also an element of the Muscogee Nation's Lanham Act claim. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1390-91 (2014) (holding that a plaintiff "ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising"). Because the Muscogee Nation's injury (increased government expenditures) does not flow "directly" from any alleged deception, this claim fails too.

State Law Claims: The lack of proximate cause also dooms the Tribes' assorted state law claims. Under both Oklahoma and Montana law, proximate cause is an element of the negligence and fraud claims brought by the Tribes. *Not Afraid v. State*, 362 P.3d 71, 74 (Mont. 2015) (negligence); *Akin v. Mo. Pac. R.R. Co.*, 977 P.2d 1040, 1054-55 (Okla. 1998) (negligence); *McNeil v. Currie*, 830 P.2d 1241, 1246 (Mont. 1992) (fraud). And because proximate cause is an essential element of *any* tort claim, it is an essential element of the Tribes' nuisance claims as well. *See* W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* § 41, at 263 (5th ed. 1984); *see also Twyman v. GHK Corp.*, 93 P.3d 51, 61 (Okla. Civ. App. 2004); *Walton v. City of Bozeman*, 588 P.2d 518, 522 (Mont. 1978). The Blackfeet Tribe's claim under Montana's Unfair Trade Practices and Consumer Protection Act (MCPA) also requires proximate cause. *See Anderson v. ReconTrust Co., N.A.*, 407 P.3d 692, 700 (Mont. 2017).

And although proximate causation is not generally listed as an "element" of unjust enrichment, it is inherent in the requirement that the defendant's retention of the benefit in question be inequitable. *See, e.g.*, *Darty v. Grauman*, 419 P.3d 116, 119 (Mont. 2018) (unjust enrichment requires an "inequitable result"); *Harvell v. Goodyear Tire & Rubber Co.*, 164 P.3d 1028, 1035 (Okla. 2006) (same). If a defendant's conduct is not the legal cause of the plaintiff's harm, justice does not require the defendant to make restitution. *See In re Light Cigarettes Mktg. Sales Practices Litig.*, 271 F.R.D. 402, 418 (D. Me. 2010) ("Although the Plaintiffs are correct that injury and causation are not elements of claims for unjust enrichment in Maine and Washington D.C., they have not established why, absent injury and causation, the Defendants' 'retention of the benefit is unjust.'"). For this reason, where, as here, an unjust enrichment claim is premised on the same theory as tort claims that have failed for lack of proximate causation, the unjust enrichment claim fails as well. *Perry*, 324 F.3d at 851.

Lastly, numerous cases concluding that RICO claims fail on proximate causation grounds have recognized that parallel state common law claims fail for the same reason. *See, e.g.*, *Steamfitters*, 171 F.3d at 934-35 (fraud and unjust enrichment); *SEIU Fund*, 249 F.3d at 1076 n.6 (fraud); *Hospital Districts*, 241 F.3d at 706-07 (fraud and nuisance). In *Perry*, for instance, the Sixth Circuit observed that because "the RICO statute incorporates general common law principles of proximate causation," "a claim-by-claim analysis" was unnecessary. 324 F.3d at 850 (dismissing negligence claim for same reason as RICO claim); *see also Hospital Districts*, 241 F.3d at 707 ("The proximate cause test for . . . RICO standing is the common law proximate cause test."). Nothing suggests that Montana or Oklahoma have idiosyncratic notions of proximate cause that deviate from the general common law. The Court should therefore dismiss all the state law claims for lack of proximate cause.

B. The Tribes' Negligence Claims Also Fail To Establish Any Duty To Prevent The Misconduct Of Third Parties

The Tribes' negligence claims fail for an additional (albeit related) reason: the Manufacturers do not owe the Tribes any duty to anticipate or prevent the criminal, intentional, or reckless conduct of others—including distributors, pharmacies, doctors, drug dealers, opioid users, and various other intermediaries.

Whether a duty of care exists and the scope of any such duty are questions of law for the Court. *Poole v. Poole*, 1 P.3d 936, 939 (Mont. 2000); *Wofford v. E. State Hosp.*, 795 P.2d 516, 521 (Okla. 1990). Under both Montana and Oklahoma law, a defendant generally has no duty to anticipate or prevent the criminal, intentional, or reckless behavior of third parties unless there is a special relationship of custody or control between the defendant and either the third party or the injured party. *See Lopez v. Great Falls Pre-Release Servs., Inc.*, 986 P.2d 1081, 1086 (Mont. 1999) ("As a general rule, there is no duty to protect others against harm from third persons."

(citing W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* § 56, at 385 (5th ed. 1984))); *Thornton v. Ford Motor Co.*, 297 P.3d 413, 428 (Okla. Civ. App. 2012) ("[A]bsent either *special relations* or *special circumstances*, a defendant has neither a duty of care to the plaintiff nor a duty to anticipate or control the intentional and criminal acts of a third person against that plaintiff."). Oklahoma courts have likewise rejected the existence of any tort duty owed to "addicts [seeking] to recover for injuries stemming from their illicit drug use." *Prince v. B.F. Ascher Co.*, 90 P.3d 1020, 1028 (Okla. Civ. App. 2004). The Manufacturers thus have no general duty to protect the Tribes from the criminal, intentional, or reckless conduct of third parties. The Tribes' claims, however, largely turn on the non-existent duty to anticipate and prevent the criminal, intentional, or reckless conduct of distributors, pharmacies, criminals, pill mills, other entities, and individuals. *See, e.g.*, Muscogee 1AC ¶¶ 208-10, 213-25, 230, 232, 237, 241-62, 278, 282, 287, 290-91, 436(c); Blackfeet 1AC ¶¶ 81, 469-73, 482-83, 494, 501, 566-72, 574-77, 586-647, 924, 983-84, 988(g), 994-95.

The Tribes do not allege any facts showing that the Manufacturers have a sufficiently special relationship of custody or control with any of the distributors, pharmacies, doctors, criminals, or other intermediate actors in the distribution chain. *See, e.g.*, *Gaines-Tabb v. ICI Explosives USA, Inc.*, 995 F. Supp. 1304, 1316-17 (W.D. Okla. 1996) (noting that special relationships include landlord-tenant, carrier-passenger, innkeeper-guest, and employer-employee, and holding that manufacturer of fertilizer had no duty to anticipate or prevent use of fertilizer in bombing); *Lopez*, 986 P2d at 1086 (special relationship requires custody or control). Without direct custody or control over these actors, and in the absence of other special circumstances, the Manufacturers owe no duty to the Tribes to control or prevent the criminal, intentional, or reckless conduct of these third parties.

Courts across the country have found, on similar facts, that no such duty exists. *See, e.g.*, *District of Columbia*, 872 A.2d at 639-45 (gun manufacturers have no duty to reduce risk of illegal gun use); *McCarthy v. Olin Corp.*, 119 F.3d 148, 157 (2d Cir. 1997) ("New York courts do not impose a legal duty on manufacturers to control the distribution of potentially dangerous products such as ammunition."); *Caveny v. Raven Arms Co.*, 665 F. Supp. 530, 536 (S.D. Ohio 1987) ("By manufacturing and distributing the handgun in this case, defendants did not breach a duty to plaintiffs under Ohio law."), *aff'd*, 849 F.2d 608 (6th Cir. 1988); *City of Chicago*, 821 N.E.2d at 1126 ("[D]efendants owe no duty to the city of Chicago or its residents to prevent their firearms from ending up in the hands of persons who use and possess them illegally."). The Tribes' negligence claims should therefore be dismissed to the extent they turn on the criminal, intentional, or reckless conduct of third parties.

II. THE TRIBES' ALLEGED INJURIES ARE NOT REDRESSABLE AND THEY LACK STATUTORY STANDING TO BRING MANY OF THEIR CLAIMS

The Tribes are not authorized to recover for any of their alleged harms. The Tribes cannot recover for the costs of providing health care because those costs are either paid by the federal government (not the Tribes), or governed by a federal statute that the Tribes neither invoke nor satisfy. The Tribes also cannot recover the costs of providing public services. Moreover, none of the statutes the Tribes rely on is intended to protect them, or any other government entity, from the sorts of harms alleged. This fundamental mismatch is fatal to the Tribes' RICO, Lanham Act, Montana Consumer Protection Act, and negligence per se claims.

A. The Tribes Cannot Recover The Costs Of Providing Health Care

Both Tribes seek to recover the costs of medical care provided to their members as a result of the Manufacturers' alleged misconduct. *See* Muscogee 1AC ¶¶ 22, 351, 443; Blackfeet 1AC ¶¶ 19, 678, 852. But the Tribes are foreclosed from recovering these costs because their members'

healthcare is funded and governed by federal law. To the extent their members received care provided by the Indian Health Service (IHS)—an agency of the federal government—the Tribes lack standing to recover the costs of that care. And to the extent medical costs were instead funded by a compact (or contract) under the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. § 5301 *et seq.*, the Tribes' ability to recover is statutorily governed by the Federal Medical Care Recovery Act (MCRA), 42 U.S.C. § 2641 *et seq.*, under which they must identify the *specific individuals* whose medical costs they seek to recover. They have not and so, either way, the Tribes' pursuit of medical costs fails as a matter of law.[5]

1. The Tribes Lack Standing To Recover Costs Incurred By The Indian Health Service

To the extent that the Tribes seek to recover the costs of medical care provided directly by IHS, they lack standing to seek such damages because they have suffered no injury. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000) ("[A] plaintiff must demonstrate standing separately for each form of relief sought."). The reason is simple: The cost of that care was borne by the United States, not the Tribes. Only the United States has standing to recover the cost of any direct expenditures by IHS. *Acoma Pueblo v. Am. Tobacco Co.*, slip op. at 8-9, No. 99-CV-1049 (D.N.M. July 30, 2001) (rejecting Indian tribes' argument that "they are entitled to recover monies expended on their behalf by the federal government").[6]

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[5] The Muscogee Nation alleges that it provides healthcare to its members under an ISDEAA compact. Muscogee 1AC ¶ 26. The Blackfeet Tribe does not allege whether its members receive care through IHS or through ISDEAA funding, but as explained, it cannot recover under either scenario.

[6] A copy of *Acoma Pueblo* is attached to the Morris Declaration as Exhibit B.

2. The Tribes Cannot Recover Compact Funds Because They Have Failed To Identify The Individual Patients At Issue

To the extent the Tribes seek to recover medical costs funded under the ISDEAA, federal law—specifically, MCRA—governs and provides the Tribes no remedy in this case. *See* 25 U.S.C. § 1621e.

Before 2010, tribes had no authority to recover damages from a third-party tortfeasor. Instead, the applicable statute only allowed a tribe to recover from *an insurer* the "reimbursement or indemnification" that the insurer would normally owe to the injured party. 25 U.S.C. § 1621e(a) (2006); *see also* S. Rep. No. 102-392, at 20-21 (1992) (explaining that this provision provided "a right of recovery against private insurers with respect to expenses incurred . . . in providing health services"). In 2010, as part of the reauthorization of the Indian Healthcare Improvement Act, Congress revised § 1621e to allow tribes to seek "*damages*, reimbursement, or indemnification" against not only insurers but also (among others) "third-party tortfeasor[s]." 25 U.S.C. § 1621e(a) (2012) (emphasis added). More specifically, a tribe operating under an ISDEAA compact that "furnish[es] or pay[s] for health services to a person who is injured or suffers a disease on or after March 23, 2010, under circumstances that establish grounds for a claim of liability against [a] tortfeasor" may recover—from the tortfeasor—the "reasonable value" of those services "in accordance with [MCRA], to the same extent and under the same circumstances as the United States may recover under that Act." *Id.* § 1621e(e)(3)(A). Congress made clear that this revision "extend[s] to Tribes and Tribal Organizations the same authority the U.S. has under [MCRA] to recover the costs of medical care from a tortfeasor." S. Rep. No. 110-197, at 61 (2007).[7]

[7] MCRA was enacted in response to *United States v. Standard Oil Co.*, 332 U.S. 301 (1947), which held that the United States lacked a common-law cause of action to recover from third-party tortfeasors medical expenses it incurred providing healthcare to military personnel. Just as the United States could not recover such federal expenditures from third-party tortfeasors until

But § 1621e limits the ability of the Tribes to recover in two key respects. First, the Tribes cannot recover any healthcare expenditures for injuries occurring before March 23, 2010. 25 U.S.C. § 1621e(e)(3)(A) (covering services provided "to a person who is injured or suffers a disease on or after March 23, 2010"). Second, for costs that are not time-barred, the Tribes can only recover "to the same extent and under the same circumstances as the United States may recover under" MCRA. *Id.* And courts have placed important restrictions on the United States' ability to recover under MCRA—restrictions that apply with equal force to the Tribes.

In particular, under MCRA, the United States must identify the *specific individuals* whose medical costs they incurred and seek to recover. In *United States v. Philip Morris Inc.*, 153 F. Supp. 2d 32 (D.D.C. 2000), the United States (much like the Tribes here) sought to recover from tobacco companies the increased healthcare costs it incurred as a result of its beneficiaries' smoking. But the court held that the government's claims failed at the outset because it had "not identified in its complaint the injured persons on whose behalf it seeks to recover under MCRA." *Id.* at 39. The court noted that because MCRA grants the government a right to recover the costs of healthcare provided "to *a person*," 42 U.S.C. § 2651(a) (emphasis added), "both logic and the plain language of the statute dictate that the Government must identify this 'person' to recover." 153 F. Supp. 2d at 39 n.11. Moreover, the same provision also states that the United States' right to recovery is "subrogated" to any claims of the injured person, and so presumes the existence of an underlying injured person. *See id.* at 38. Thus, the court held, because "the existence of legally injured persons is a prerequisite for and an essential element of the Government's MCRA claim, it must be pleaded in the complaint." *Id.* at 38.

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authorized by Congress through MCRA, so too Indian tribes could not recover until authorized by Congress through the 2010 amendments to § 1621e.

So too here. The current version of § 1621e—enacted *after Philip Morris*—likewise allows recovery for services provided "to *a person*" and is expressly tied to MCRA and incorporates its subrogation principles. 25 U.S.C. § 1621e(e)(3)(A) (emphasis added). Thus, to obtain the recovery authorized by § 1621e, a tribe must identify the particular injured persons who have "grounds for a claim of liability against the tortfeasor." *Id.* The Tribes have not identified a single such person in their complaints.

The Tribes have not even attempted to comply with this requirement. Instead, "[b]y suing directly, [the Tribes] seek to recover even if none of their beneficiaries could prevail in tort litigation." *Teamsters*, 196 F.3d at 821. But this effort to "dodge[]" the key questions of liability "is exactly why plaintiffs must lose." *Id.* at 823. Consistent with "more than 100 years" of state and federal common law (*id.* at 822), § 1621e requires the Tribes to identify the particular individuals who allegedly incurred medical expenses as a result of the Manufacturers' tortious conduct. Because the Tribes have not done so, all claims seeking to recoup medical costs should be dismissed.

B. The Tribes Cannot Recover The Costs Of Providing Public Services

The Tribes seek to recover the costs of providing their members with public services which, they allege, have increased as a result of the illegal conduct associated with the criminal misuse of opioids. But as multiple courts have recognized, the common law simply does not allow governmental entities to recover public expenditures made in the performance of government functions absent statutory authorization. *See, e.g.*, *Cty. of Erie v. Colgan Air, Inc.*, 711 F.3d 147, 150-51 (2d Cir. 2013); *Canyon Country v. Syngenta Seeds, Inc.*, 519 F.3d 969, 979 (9th Cir. 2008); *District of Columbia v. Air Florida, Inc.*, 750 F.2d 1077, 1080 (D.C. Cir. 1984); *City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322, 323 (9th Cir. 1983) (Kennedy, J.); *City of Philadelphia v. Beretta U.S.A., Corp.*, 126 F. Supp. 2d 882, 894-95 (E.D. Pa. 2000), *aff'd on other*

grounds, 277 F.3d 415 (3d Cir. 2002). Here, too, "it is the identity of the claimant and the nature of the cost that combine to deny recovery." *City of Flagstaff*, 719 F.2d at 324.

The "municipal cost recovery rule" or "free public services doctrine" is based on both the separation of powers and on the public's settled expectations. Because "the government's decision to provide tax-supported services is a legislative policy determination," "[i]t is not the place of the courts to modify such decisions" via tort law. *Air Florida*, 750 F.2d at 1080; *see also City of Chicago*, 821 N.E.2d at 1143-44; *cf. United States v. Standard Oil Co.*, 332 U.S. 301, 314-16 (1947) (declining to recognize cause of action by federal government to recover costs of injured soldier's hospitalization resulting from defendants' negligence because Congress "is the custodian of the national purse" and the "exclusive arbiter of federal fiscal affairs"). The legislature decides whether and how to expend funds to address social issues and may seek to recover such costs via statute, appropriately weighing the important policy implications of such a decision in a way the judiciary cannot. *See Air Florida*, 750 F.2d at 1080; *City of Flagstaff*, 719 F.3d at 324. To the extent governmental expenditures have increased as a result of the illegal actions of others, the proper recourse is to appeal to the legislature—not the courts. Moreover, allowing recovery of such costs through a lawsuit would upset the settled expectations of "business entities and individuals, as well as their insurers." *City of Flagstaff*, 719 F.2d at 323. When governmental entities provide services, businesses and individuals do not expect later demands by the government for reimbursement for such services. *Id.*; *see also City of Chicago*, 821 N.E.2d at 1144.

For these reasons, federal courts have rejected similar suits by governmental entities seeking recovery of the costs of providing government services—even when state law has not explicitly addressed the issue. *See Air Florida*, 750 F.2d at 1079-80; *City of Flagstaff*, 719 F.2d

at 323-24. As these courts have recognized, allowing such recovery would amount to a major expansion of liability—something federal courts should avoid when interpreting state law. *See City of Miami v. Bank of Am. Corp.*, 800 F.3d 1262, 1288 (11th Cir. 2015) (affirming dismissal of unjust enrichment claim partially because "it's not clear that municipal expenditures are among the types of benefits that can be recovered by unjust enrichment under Florida law"), *rev'd on other grounds*, 137 S. Ct. 1296 (2017); *cf. Germain v. Teva Pharm., USA, Inc. (In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.)*, 756 F.3d 917, 937 (6th Cir. 2014) (federal courts should not expand liability under state law). Because neither Montana nor Oklahoma has clearly authorized such recovery, and because the common law is to the contrary, the Court should dismiss the Tribes' claims to the extent they seek to recover the costs of government services generally recognized as unrecoverable.

C. The Tribes Fail To State A Claim Under RICO Because They Do Not Allege An Injury To Their "Business or Property"

Only a person "injured in his *business or property*" can recover under RICO's civil remedy provision, 18 U.S.C. § 1964(c). *Kramer v. Bachan Aerospace Corp.*, 912 F.2d 151, 154 (6th Cir. 1990) (emphasis added). "When a government sues under the civil RICO statute, the 'business or property' element requires that the injury 'refer to *commercial* interests or enterprises.'" *Welborn v. Bank of New York Mellon Corp.*, 557 F. App'x 383, 387 (5th Cir. 2014) (emphasis added) (quoting *Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 264 (1972)). "[T]he phrase 'commercial interests,'" in turn, "refer[s] to the interests of the [government]," not as a sovereign or provider of public services, but rather "as a party to a commercial transaction." *Town of W. Hartford v. Operation Rescue*, 915 F.2d 92, 103 (2d Cir. 1990) (quoting *Reiter v. Sonotone Corp.*,

442 U.S. 330, 341-42 (1979)).[8] Accordingly, a sovereign, like the Tribes here, cannot claim damages for injury to the "general economy" or to "the [g]overnment's ability to carry out its functions." *Hawaii*, 405 U.S. at 263-65. Instead, a government's recovery under § 1964(c) is limited to "injuries suffered" as a market participant or "in its capacity as a consumer of goods and services." *Id.*; *see also Illinois v. Life of Mid-Am. Ins. Co.*, 805 F.2d 763, 767 (7th Cir. 1986) (holding that a government does not suffer an injury to "business or property" when it sues on behalf of its citizens in a *parens patriae* capacity).

The statute's strict definition of "business or property" is fatal to the Tribes' RICO claims. The injuries that the Tribes assert are all precisely the type for which a local government cannot recover under RICO. The Tribes first allege that they are injured because they must pay increased costs for "healthcare," "mental-health services," "police," "first responders" and other "public services" to address the opioid crisis. Blackfeet 1AC ¶¶ 852, 883; *see also* Muscogee 1AC ¶ 351 (similar). But "[w]hen a governmental body acts in its sovereign or quasi-sovereign capacity, seeking to enforce the laws or promote the public well-being, it cannot claim to have been injured in its property for RICO purposes." *Canyon Cty.*, 519 F.3d at 976. Because "[a]ll government actions require the expenditure of money . . . insofar as the government acts through public servants who are paid for their services," a rule that permits "government expenditures" to constitute "injury to property" would give the government standing to sue whenever "any RICO predicate act . . . provoked any sort of governmental response." *Id.* The requirement that a governmental entity may only seek recovery as a market participant prevents that limitless

[8] *Hawaii* and *Reiter* are antitrust cases, but "Congress modeled § 1964(c) on the civil-action provision of the federal antitrust laws," and the provisions have been interpreted co-extensively. *Holmes*, 503 U.S. at 267-68 (interpreting § 1964(c)'s proximate cause requirement as equivalent to that in the antitrust laws); *see Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457 (2006) (same).

conception of RICO standing.

The Tribes also assert that they have been injured by a diminution of tax revenue, a "[l]oss of productivity" in the local population, a decline in property values, and "decreased business investment" in the community. Blackfeet 1AC ¶¶ 852, 883; Muscogee 1AC ¶ 351 (asserting injury because of "lost productivity, economic opportunity, and tax revenue"). But those are quintessential injuries to the "general economy." And as the Supreme Court has held, if a governmental entity could "recover damages for injury to its general economy, [it] would open the door to duplicative recoveries," because a "large and ultimately indeterminable part of the injury to the 'general economy' . . . is no more than a reflection of injuries to the 'business or property' of consumers." *Hawaii*, 405 U.S. at 263-64; *see also Dillon v. Combs*, 895 F.2d 1175, 1177 (7th Cir. 1990) ("RICO does not authorize a state to obtain relief on account of a fraud practiced against its residents.").[9] The generalized economic harm allegedly suffered by the Tribe and its citizens therefore also does not constitute an injury to "business or property" within the meaning of RICO.[10]

Accordingly, the Tribes lack standing to bring their RICO claims, and those counts should be dismissed in their entirety. *See also Summit* MTD §§ II.A.2, II.A (advancing some similar arguments).

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[9] The Tribes' reliance on lost tax revenue is unavailing for two further reasons as well. *First*, loss of overall tax revenue is too generalized an injury to support Article III standing. *See Arias v. DynCorp*, 752 F.3d 1011, 1015 (D.C. Cir. 2014). And, *second*, hypothetical taxes that the Tribes allege they *would collect* if not for the effects of the opioid crisis are not *current* "property" of the government, and therefore such losses cannot form the basis of alleged violations of the mail and wire fraud statutes. *See Cleveland v. United States*, 531 U.S. 12, 15 (2000).

[10] The Tribes also assert that the "health and welfare of the[ir] citizens . . . has been injured." Muscogee 1AC ¶ 351; Blackfeet 1AC ¶ 1110 (noting harm to citizens' "health, safety, and welfare"). It is well-settled, however, that "both personal injuries and pecuniary losses flowing from those personal injuries fail to confer relief under § 1964(c)." *Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565-66 (6th Cir. 2013) (en banc).

D. The Muscogee Nation's Lanham Act Claim Fails

The Muscogee Nation also pleads a Lanham Act claim for false advertising. But the Lanham Act protects *competitors* from harm to their *commercial* interests. The Muscogee Nation does not compete with the Manufacturers, and it does not allege commercial harm. Its Lanham Act claim should therefore be dismissed.

"[T]o come within the zone of interests in a suit for false advertising under [15 U.S.C.] § 1125(a), a plaintiff must allege an injury to a *commercial interest in reputation or sales*." *Lexmark*, 134 S. Ct. at 1390 (emphasis added). As the Supreme Court explained, "a plaintiff suing under § 1125(a) ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that that occurs when deception of consumers causes them to withhold trade from the plaintiff." *Id.* at 1391. Although "in the end consumers also benefit from the [Lanham] Act's proper enforcement, *the cause of action is for competitors*, not consumers." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014) (emphasis added). A cause of action under the Lanham Act is reserved for competitors to sue other competitors—and, clearly, the Tribes are not competitors of the Manufacturers.

Ignoring these principles, the Muscogee Nation claims that the Manufacturers misrepresented the safety and efficacy of prescription opioids and thus "diverted patients from hospitals and clinics run by the Nation" to "instead seek[] care from doctors and clinics who prescribed high dosages of opioids." Muscogee 1AC ¶ 415. That claim flouts *Lexmark* in two ways. *First*, the Manufacturers are not competitors of hospitals; the two do not compete for patients. *Second*, the Nation does not allege that this "diversion" from Nation hospitals and clinics injured the Nation by causing lost business or sales due to fewer patients. Instead, the Nation alleges that "[b]ut for" this diversion, "patients would have sought alternative, safer forms of treatment offered by the Nation's hospitals and clinics." *Id.* ¶ 416. This injury is not commercial

but relates to the health of Nation members who are, at most, consumers of health services. Neither health nor consumer interests are actionable under the Lanham Act. *See POM Wonderful*, 134 S. Ct. at 2234 ("[T]he cause of action is for competitors, not consumers."); *cf. Lexmark*, 134 S. Ct. at 1393 ("the sorts of commercial interests the Act protects" are "lost sales and damage to its business reputation"). Because the Lanham Act neither recognizes the Nation as a proper plaintiff nor recognizes the injuries suffered as a cognizable injury, this claim should be dismissed.

E. The Blackfeet Tribe's Montana Unfair Trade Practices And Consumer Protection Act Claim Fails

The Blackfeet Tribe also alleges a claim under the Montana Unfair Trade Practices and Consumer Protection Act (MCPA). *See* Blackfeet 1AC ¶¶ 1107-19. But because the MCPA protects only "consumers," and the Tribe does not qualify as one, it is not a proper plaintiff and its MCPA claim should be dismissed.

The MCPA makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mont. Code Ann. § 30-14-103. The MCPA provides a cause of action to "[a] *consumer* who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act, or practice declared unlawful by 30-14-103." *Id.* § 30-14-133(a) (emphasis added). Under the statute, "'[c]onsumer' means a person who purchases or leases goods, services, real property, or information *primarily for personal, family, or household purposes*." *Id.* § 30-14-102(1) (emphasis added). As the statutory text makes plain, an MCPA plaintiff must therefore have conducted a "consumer transaction" with the defendant. *See Fink v. Meadow Lake Estates Homeowners' Ass'n*, 384 Mont. 552, 2016 WL 2668136, at *4 (May 10, 2016); *cf. Brookins v. Mote*, 292 P.3d 347, 360 (Mont. 2012) ("[O]nly those acts or practices in the conduct of entrepreneurial, commercial, or business aspects of running a hospital are actionable under Montana's CPA.").

Courts have therefore consistently dismissed MCPA and similar statutory consumer protection claims when the plaintiff is not a consumer. *See, e.g.*, *Doll v. Major Muffler Ctrs., Inc.*, 687 P.2d 48, 52 (Mont. 1984) (owner of automobile repair service); *In re Lidoderm Antitrust Litig.*, 103 F. Supp. 3d 1155, 1165 (N.D. Cal. 2015) (health plan provider); *In re Auto. Parts Antitrust Litig.*, No. 12-MD-02311, 2013 WL 2456612, at *30 (E.D. Mich. June 6, 2013) (automotive dealers).

The Tribe does not qualify as a "consumer" under the MCPA. At the most basic level, the Blackfeet Tribe, as a sovereign entity, does not (and cannot) allege that it purchased items, such as pharmaceutical medications, from the Manufacturers for "personal, family, or household purposes." *See* Mont. Code Ann. § 30-14-102(1) (defining "[c]onsumer"). The Blackfeet Tribe did not purchase any items from the Manufacturers at all, and it certainly did not do so for such purposes. The complaint also does not (and cannot) allege that the Tribe suffered any *consumer*—as opposed to sovereign or municipal—injuries arising out of any consumer transaction between the Tribe and the Manufacturers. *See* Blackfeet 1AC ¶ 1114 (alleging injuries unique to sovereign entity); *see also* Mont. Code Ann. § 30-14-133(1) (cause of action designed to remedy consumer injuries arising out of a consumer transaction); *see also Higgins v. First Horizon Nat'l Corp.*, No. 15-CV-101, 2018 WL 1203474, at *11 (D. Mont. Mar. 8, 2018).

Nor does the MCPA provide for enforcement by tribes. The MCPA explicitly authorizes the Montana Department of Justice and district attorneys to bring claims for injunctive relief on behalf of the State, but it makes no mention of any analogous authority for tribes. Mont. Code Ann. §§ 30-14-111(1), 30-14-121. The inclusion of authority for the Department and district attorneys without a similar provision for tribes strongly implies that tribes lack such authority. *See Westmoreland Res. Inc. v. Dep't of Revenue*, 330 P.3d 1188, 1191 (Mont. 2014) (tax statute referring expressly to "federal, state, or local governments" did *not* encompass tribal

governments); *State ex rel. Jones v. Giles*, 541 P.2d 355, 357 (Mont. 1975) ("[A]n express mention of a certain power or authority implies the exclusion of nondescribed powers."). Moreover, the MCPA provides that a consumer "may bring an individual but not a class action." Mont. Code Ann. § 30-14-133(1). That prohibition on class actions evinces a legislative preference for individualized actions, as opposed to the quasi-collective action that the Blackfeet Tribe asserts. Accordingly, the MCPA claim should be dismissed.

F. The Tribes Fail To Allege Any Statutory Violation Sufficient To Support Their Negligence Per Se Claims

The Tribes' negligence per se claims fail for similar reasons. To state a claim for negligence per se, the Tribes must allege, among other things, that (i) the Manufacturers violated a statute that was specifically enacted to protect the Tribes, and (ii) the statute was enacted to prevent the type of injury that forms the basis of the Tribes' suits. *See*, *e.g.*, *Patten v. Raddatz*, 895 P.2d 633, 638 (Mont. 1995); *Ohio Cas. Ins. Co. v. Todd*, 813 P.2d 508, 510 (Okla. 1991). In Montana, "the statute allegedly violated" must also "allow[] a private right of action." *Doyle v. Clark*, 254 P.3d 570, 577 (Mont. 2011). The Tribes fail to satisfy these requirements.

The complaints identify the provisions of only three statutes allegedly violated by the Manufacturers: the Controlled Substances Act (CSA) (including 21 U.S.C. §§ 823 and 827(d)(1)), the Federal Food Drug, and Cosmetic Act (FDCA), and Mont. Code Ann. § 37-7-604. *See* Blackfeet 1AC ¶ 1021; Muscogee 1AC ¶¶ 97, 435. But the Tribes are not intended beneficiaries of the CSA or the FDCA, and the Blackfeet Tribe is not an intended beneficiary of the Montana statute. Even if they were, these statutes were not designed to prevent the types of harms that the Tribes are alleging. *See Patten*, 895 P.2d at 638; *Ohio Cas. Ins. Co*, 813 P.2d at 510; *Been v. MK Enter., Inc.*, 256 P.3d 1040, 1044 (Okla. Civ. App. 2011).

To begin, § 823 of the CSA outlines the requirements an applicant must meet for the U.S.

Attorney General to register that applicant to manufacture controlled substances. *See, e.g.*, 21 U.S.C. § 823(a), (b). Section 827(d) sets forth a reporting requirement to the U.S. Attorney General. *See, e.g., id.* § 827(d)(1). Neither provision includes the Tribes in a protected statutory class or provides protection to the Tribes for their asserted injuries. *See, e.g., Carmack v. UPMC*, No. G-D-14-013571, 2015 Pa. Dist. & Cnty. Dec. LEXIS 14730, at *26-27 (Pa. D. & C. Jan. 12, 2015) (CSA not "designed to provide any protections other than to the public at large."). In any event, the Supreme Court and the Sixth Circuit repeatedly have made clear that state law claims premised on the Manufacturers' alleged violation of the CSA—and the FDCA—are preempted by federal law, because enforcement of those laws is delegated exclusively to federal authorities. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives"); *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d at 936 (any attempt to enforce the FDCA through a state-law claim would be preempted); *Durr v. Strickland*, 602 F.3d 788, 789 (6th Cir. 2010) (affirming ruling that "no private right of action exists under" CSA); *see also Estep v. Danek Med., Inc.*, No. 1:96-CV-2580, 1998 WL 1041330, at *2 (N.D. Ohio Dec. 8, 1998) ("State law allowing negligence per se under the FDCA would result in circumvention of Congress' intent to preclude private enforcement."); *Safe Sts. Alliance v. Alternative Holistic Healing, LLC*, No. 1:15-cv-00349, 2016 WL 223815, at *3 (D. Colo. Jan. 19, 2016), *aff'd*, 859 F.3d 865 (10th Cir. 2017); *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346, 1355 (S.D. Fla. 2003) (finding no private right of action or remedy exists under 21 U.S.C. § 823). Thus, neither the CSA nor the FDCA can form the basis of a negligence per se claim.

Similarly, Mont. Code Ann. § 37-7-604 requires a manufacturer to obtain a license and pay

a fee, meet certain other requirements, and agree to comply with state and federal law. *See* Mont. Code Ann. § 37-7-604(1), (2); *see also* Blackfeet 1AC ¶ 653. As with the CSA, Mont. Code Ann. § 37-7-604 does not seek to protect the Blackfeet Tribe or redress the Tribe's claimed injuries. *See, e.g.*, *Patten*, 895 P.2d at 638; *see also Doyle*, 360 Mont. at 458, 254 P.3d at 576-77. The Nation's negligence per se claim premised on a violation of the Oklahoma Uniform Dangerous Controlled Substances Act similarly fails. Oklahoma law has refused to impute civil liability for failure to comply with a mandatory reporting statute, particularly when, as is the case here, the cited statute does not create a private right of action or an avenue for civil liability. *See, e.g.*, *Paulson v. Sternlof*, 15 P.3d 981, 984 (Okla. Civ. App. 2000).

Finally, to the extent the Blackfeet Tribe seeks to assert a negligence per se claim based on the violation of a regulation, that claim fails as a matter of law. *See, e.g.*, Blackfeet 1AC ¶¶ 1007, 1009, 1015, 1018, 1020-22. To be liable for negligence per se, "the defendant must have violated a *statute*, as opposed to merely an administrative regulation, safety code, or professional standard." *Harwood v. Glacier Elec. Coop., Inc.*, 949 P.2d 651, 656 (Mont. 1997). Accordingly, any claims premised on a regulatory violation are not actionable, and the negligence per se claim should be dismissed in its entirety.

III. THE TRIBES INVOKE COMMON LAW CAUSES OF ACTION THAT ARE NOT INTENDED TO COVER THE ALLEGED MISCONDUCT

The alleged wrongful conduct that the Tribes attempt to impute to the Manufacturers largely sounds in fraud. As discussed throughout this Memorandum, the Tribes' fraud-based claims, whether framed under a RICO, negligence, or consumer protection theory, fail for multiple reasons. The Tribes also raise claims of public nuisance and unjust enrichment. The Court should reject the Tribes' effort to expand these doctrines in ways wholly unsupported by existing Oklahoma and Montana case law. Public nuisance is primarily concerned with the misuse of and

interference with real property; it is not a freewheeling form of products liability. Nor is unjust enrichment, which is concerned with quasi-contracts and is not the basis for recovering the costs of public services.

A. The Tribes' Public Nuisance Claims Fail

Both Tribes claim that the Manufacturers' marketing of their products has created a public nuisance. Muscogee 1AC ¶¶ 419-32; Blackfeet 1AC ¶¶ 888-974. Indeed, the Blackfeet Tribe tries to plead three different versions of this claim under Montana's nuisance statute and federal and state common law. All of these claims fail for a fundamental reason: they rest on a novel theory of public nuisance that finds no support in the case law and that collapses the critical distinction between nuisance and products liability law.

1. Neither Oklahoma Nor Montana Law Recognizes The Tribes' Novel, Products Liability Theory Of Public Nuisance

Both Tribes plead a theory of public nuisance that is unrecognizable in the eyes of Oklahoma and Montana law. The nuisance claims are essentially products liability claims for economic damages masquerading under the guise of nuisance law. As such, they are improper and should be dismissed.

Oklahoma law provides that "[a] nuisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either . . . [a]nnoys, injures or endangers the comfort, repose, health, or safety of others; or . . . [i]n any way renders other persons insecure in life, or in the use of property." Okla. Stat. tit. 50, § 1. Montana similarly defines a "nuisance" as "[a]nything that is injurious to health, indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property." Mont. Code Ann. § 27-30-101(1). Both States, in turn, define a "public nuisance" as any nuisance "which affects, at the same time, an entire community or neighborhood or any considerable number of persons,

although the extent of the annoyance or damage inflicted upon individuals may be unequal." Okla. Stat. tit. 50, § 2; Mont. Code Ann. § 27-30-102(1).

The law of nuisance in both States is concerned with the misuse of, or interference with, land and real property. *See, e.g.*, *Laubenstein v. Bode Tower, L.L.C.*, 392 P.3d 706, 709 (Okla. 2016) ("We have said that a nuisance arises from an unreasonable, unwarranted, or unlawful use of property."); *Graveley Ranch v. Scherping*, 782 P.2d 371, 373 (Mont. 1989) (holding that "the presence of exposed lead batteries on defendants' property . . . sufficiently interfered with plaintiff's use of property for grazing so as to constitute a nuisance"); *see also State v. Lead Indus. Ass'n, Inc.*, 951 A.2d 428, 452-53 (R.I. 2008) (discussing the history of public nuisance's ties to land). No case in either state embraces the Tribes' view that public nuisance encompasses harm caused by the marketing and sale of allegedly harmful products.

A survey of public nuisance cases in Oklahoma and Montana reveals a consistent theme of interference with the use and enjoyment of real property. For example, many Oklahoma public nuisance decisions concern the pollution of land or water. *See, e.g.*, *N.C. Corff P'ship, Ltd. v. OXY USA, Inc.*, 929 P.2d 288, 293-96 (Okla. Civ. App. 1996) (groundwater pollution from oil and gas wells); *Meinders v. Johnson*, 134 P.3d 858, 860, 867-68 (Okla. Civ. App. 2005) (subsurface pollution from mineral exploration). Others concern the misuse of private property for other sorts of obnoxious, dangerous, or immoral purposes. *See, e.g.*, *State ex rel. Fallis v. Mike Kelly Constr. Co.*, 638 P.2d 455, 455 (Okla. 1981) (operation of "open saloon"); *Boudinot v. State ex rel. Cannon*, 340 P.2d 268, 269 (Okla. 1959) ("noise and odor arising" from defendant's "keeping a large number of cats on her residential property"). And others concern the misuse of public lands and roads. *See, e.g.*, *State ex rel. Burk v. Oklahoma City*, 522 P.2d 612, 615 (Okla. 1973) (construction of building on public street). Montana public nuisance cases likewise focus on the

use of real property. *See, e.g.*, *State ex rel. Dep't of Envtl. Quality v. BNSF Ry. Co.*, 246 P.3d 1037, 1040 (Mont. 2010) (groundwater and soil pollution); *State ex rel. Fields v. Dist. Ct. of First Judicial Dist.*, 541 P.2d 66, 67 (Mont. 1975) (keeping of dangerous dog on property); *Kasala v. Kalispell Pee Wee Baseball League*, 439 P.2d 65, 66-69 (Mont. 1968) (Pee Wee baseball league's use of playground).

The Tribes' claims stand far outside this legal tradition and do not remotely resemble the types of public nuisance claims traditionally permitted by Montana and Oklahoma courts. Their claims have virtually nothing to do with the misuse of or interference with property. The Tribes do not plausibly allege that the Manufacturers are unlawfully misusing their own property or that their conduct is unlawfully interfering with the Tribes' (or their members') land or property. Instead, the Tribes allege that they have suffered economic damages for alleged derivative expenses (*e.g.*, healthcare costs, social services, criminal justice) arising from the marketing and sale of allegedly harmful products and injuries to consumers of those products. *See* Blackfeet 1AC ¶ 945; Muscogee 1AC ¶ 431. In other words, the Tribes' claims sound entirely in products liability, not nuisance. Nuisance and product liability are separate and distinct bodies of law, and courts across the nation have held that they must remain that way.

For example, the Rhode Island Supreme Court has refused to hold lead paint manufacturers liable under a public nuisance theory. "The law of public nuisance," the court recognized, "never before has been applied to products, however harmful." *Lead Indus.*, 951 A.2d at 456. The court explained that while "[p]ublic nuisance focuses on the abatement of annoying or bothersome activities[,] [p]roducts liability law, on the other hand, has its own well-defined structure, which is designed specifically to hold manufacturers liable for harmful products that the manufacturers have caused to enter the stream of commerce." *Id.* "Undoubtedly, public nuisance and products

liability are two distinct causes of action, each with rational boundaries that are not intended to overlap." *Id.*; *see also id.* at 457.

A host of other state and federal courts—in cases involving a wide array of products—have agreed that public nuisance liability is not a substitute for products liability. *See, e.g.*, *Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp.*, 273 F.3d 536, 540 (3d Cir. 2001) (firearms) ("[T]he courts have enforced the boundary between the well-developed body of product liability law and public nuisance law."); *Ashley Cty.*, 552 F.3d at 671-72 (cold medicine) (same); *City of Perry v. Procter & Gamble Co.*, 188 F. Supp. 3d 276, 291 (S.D.N.Y. 2016) (flushable wipes) ("The parties do not cite, and the Court is not aware of, any cases applying Iowa law that recognize a nuisance claim arising out of the sale or use of a product as opposed to the use of property."); *Detroit Bd. of Educ. v. Celotex Corp.*, 493 N.W.2d 513, 520 (Mich. Ct. App. 1992) (asbestos) ("The law of nuisance is fraught with conditional rules and exceptions that turn on the facts of individual cases, and the cases almost universally concern the use or condition of property, not products.").[11]

Indeed, there are good reasons for not letting public nuisance expand in this way: Allowing a products-based claim to proceed under a nuisance theory would eviscerate "the strict requirements that surround a products liability action." *Lead Indus.*, 951 A.2d at 456. For

[11] The drafters of the Third Restatement of Torts have noted and approved this trend, observing that "the common law of public nuisance is an inapt vehicle for addressing the conduct at issue" in cases of dangerous products. Restatement (Third) of Torts: Liability for Economic Harm § 8 TD No. 2 cmt. g (2014). Commentators have likewise criticized efforts to wield public nuisance liability as a club against product manufacturers. *See, e.g.*, Victor E. Schwartz & Phil Goldberg, *The Law of Public Nuisance: Maintaining Rational Boundaries on a Rational Tort*, 45 Washburn L.J. 541, 543 (2006) ("The current effort to expand public nuisance theory to provide sanctions against manufacturers of lawful products is disconcerting because it would fundamentally change the entire character of public nuisance doctrine, as well as undermine products liability law.").

example, permitting a public nuisance theory for products-based claims could require relaxing the standards for causation or alleviating a plaintiff's necessary responsibility to identify a particular product that gave rise to the injury. *City of St. Louis v. Benjamin Moore & Co.*, 226 S.W.3d 110, 116 (Mo. 2007); *Lead Indus.*, 951 A.2d at 457. Thus, recognizing such an action "would permit nuisance liability to be imposed on an endless list of manufacturers, distributors, and retailers of manufactured products." *See City of Chicago*, 821 N.E.2d at 1116. "[N]uisance law 'would become a monster that would devour in one gulp the entire law of tort.'" *Camden Cty.*, 273 F.3d at 540 (quoting *Tioga Pub. Sch. Dist. No. 15 v. U.S. Gypsum Co.*, 984 F.2d 915, 921 (8th Cir. 1993)).

This Court should reject the Tribes' efforts to drastically expand Oklahoma and Montana common law beyond their present boundaries and beyond the boundaries permitted by sister states. The "enormous leap that the [Tribes] urge[] [this Court] to take is wholly inconsistent with the widely recognized principle that the evolution of the common law should occur gradually, predictably, and incrementally." *Lead Indus.*, 951 A.2d at 454. The law of public nuisance should not be transformed into an expanded (and freewheeling) doctrine of products liability.

2. Additional Grounds Require Dismissal Of The Blackfeet Tribe's Federal And State Common Law Public Nuisance Claims

The Blackfeet Tribe's public nuisance claims under federal common law (Count III) and state common law (Count IV) face a threshold problem as well: Neither cause of action exists.

First, "federal common law constitutes an unusual exercise of lawmaking which should be indulged only in a few restricted instances" and only where "'there is a significant conflict between some federal policy or interest and the use of state law.'" *FDIC v. AmFin Fin. Corp.*, 757 F.3d 530, 535 (6th Cir. 2014) (quoting *O'Melveny & Myers v. FDIC*, 512 U.S. 79, 87 (1994)). There must be "a demonstrated need for a federal rule of decision." *Am. Elec. Power Co. v. Connecticut*,

564 U.S. 410, 422 (2011). Such a need may exist in disputes between two states or between states and the federal government, and it is only in such contexts that the Supreme Court has recognized federal common law nuisance claims. *See id.* at 421 (collecting cases). There is no need for a federal rule of decision here. Count III should be dismissed.

Second, Montana does not recognize a cause of action for "common law public nuisance." Rather, Montana has long defined the law of nuisance by statute. *See* Mont. Code Ann. §§ 27-30-101 *et seq.*; *Belue v. State*, 649 P.2d 752, 754 (Mont. 1982) (noting that these statutes are "crystallizations of the common law"). Count IV should accordingly be dismissed, as well.

B. The Unjust Enrichment Claims Fail

Like their public nuisance claims, the Tribes' unjust enrichment claims stretch that cause of action too far. In Montana, "[t]o prove unjust enrichment, the plaintiff must establish: (1) the defendant received a benefit; (2) defendant knew about or appreciated the benefit; and (3) defendant accepted or retained the benefit under circumstances where it was inequitable for defendant to do so." *Darty*, 419 P.3d at 119. Similarly, in Oklahoma, "[u]njust enrichment arises from the failure of a party to make restitution in circumstances where it is inequitable, or one party holds property that, in equity and good conscience, it should not be allowed to retain." *Am. Biomedical Grp., Inc. v. Techtrol, Inc.*, 374 P.3d 820, 828 (Okla. 2016). Through unjust enrichment, the law essentially creates an implied contract to permit recovery on principles of equity. *See Christian v. Atlantic Richfield Co.*, 358 P.3d 131, 150 (Mont. 2015) ("Unjust enrichment is traditionally conceived of as an implied contract theory requiring payment for a benefit conferred."); *French Energy, Inc. v. Alexander*, 818 P.2d 1234, 1238 (Okla. 1991) (allowing recovery based on unjust enrichment because "this case is a classic illustration of when, in accordance with general principles of common justice and equity, Appellees will be required to do what it is they promised").

Here, the Tribes both allege that the Manufacturers are "unjustly enriched" because the Tribes have "expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Marketing Manufacturer Defendants' misleading statements," Muscogee 1AC ¶ 447, including "healthcare services and treatment," and so "conferred a benefit upon Defendants by paying for Defendants' externalities," Blackfeet 1AC ¶¶ 1075, 1077. That theory fails for at least three reasons.

First, the Manufacturers have received no benefits from the Tribes. In attempting to allege that they conferred a benefit on the Manufacturers, the Tribes only vaguely refer to payments for "externalities" and expenditures "to remedy or mitigate the societal harms caused by Marketing Manufacturer Defendants' misleading statements." Muscogee 1AC ¶ 447; *see* Blackfeet 1AC ¶¶ 1075, 1077. But even assuming that the Blackfeet complaint's reference to "healthcare services and treatment" adequately identifies a benefit *to someone*, those are at most benefits provided to third-parties (*e.g.*, doctors, hospitals, citizens)—not to the Manufacturers—and thus cannot support an unjust enrichment claim. *See City of Miami*, 800 F.3d at 1288 (rejecting city's attempt to recoup costs incurred combatting effects of bank's predatory lending practices because the "municipal services were not benefits conferred directly on the Bank—the services were provided to the residents of Miami . . . and any benefit the Bank received was merely derivative").

Second, the Manufacturers never had an obligation to pay such costs. "One cannot be unjustly enriched by failing to pay a debt one does not owe." *Mont. Petroleum Tank Release Comp. Bd. v. Capitol Indem. Co.*, 137 P.3d 522, 529 (Mont. 2006); *accord Am. Biomedical Grp.*, 374 P.3d at 828 (same). The Tribes do not (and cannot) allege that the Manufacturers had a legal duty to pay for "health care services and treatment to people who use opioids" or for any of the other types of damage sought in the complaints. Unjust enrichment claims have been rejected in

similar circumstances. For example, in multiple cases, health insurers or their insureds brought unjust enrichment claims against tobacco companies, alleging that the tobacco companies were unjustly enriched because the insurers and/or the insureds had to cover higher costs for treating participants' smoking-related illnesses. Courts—including the Sixth Circuit—dismissed those claims, explaining that the plaintiffs had not enriched the defendants because tobacco companies "have no legal duty to smokers to pay their medical costs." *Perry*, 324 F.3d at 851; *see also Oregon Laborers*, 185 F.3d at 968. So too here.

Third, there is no unjust enrichment claim when a plaintiff seeks reimbursement for an expenditure it was independently required to make, even absent any implied agreement with the defendants. Courts in the tobacco cases dismissed such unjust enrichment claims because the insurance-plan plaintiffs were obligated to cover participants' expenses anyways—indeed, that is the very function of an insurance plan. *See Oregon Laborers*, 185 F.3d at 968 ("Moreover, because plaintiffs had an independent obligation to pay the smokers' medical expenses, they cannot maintain an action for unjust enrichment against defendants just because defendants were incidentally benefitted."). Similarly here, the Tribes seek compensation for government services that they, as governments, are already obligated to perform under their own laws.

Both the Montana and Oklahoma Supreme Courts have rejected efforts to expand unjust enrichment to embrace novel theories of recovery, citing both prudential and policy concerns. *See Darty*, 419 P.3d at 120 (rejecting unjust enrichment theory that would allow evasion of contract-law principles); *City of Tulsa*, 280 P.3d at 320 (rejecting unjust enrichment theory that "would have a chilling effect on economic development"). Other courts have recognized that unjust enrichment is not a mechanism for governments to obtain reimbursement for the costs of providing public services. In *Ashley County*, for example, the Eighth Circuit explained that "[t]he

circumstances connecting the sales of cold medication to the provision of these government services are simply too attenuated to give rise to an implied contract between the manufacturers and the county providers to state a cause of action for unjust enrichment." 552 F.3d at 666; *see also City of Miami*, 800 F.3d at 1287-89 (explaining why recovery for municipal services strains the theory of unjust enrichment and ultimately "declin[ing] to invent a novel basis for unjust enrichment").

The bottom line is that the Tribes' unjust enrichment claims—like their public nuisance claims—stretch a defined body of law beyond recognition. It defies common sense to believe that the Manufacturers somehow received undeserved benefits when—after the opioid medications left the Manufacturers' control—the Tribes subsequently provided its citizens with a standard array of healthcare and other public services. The Montana and Oklahoma Supreme Courts have been vigilant in checking the expansion of such novel theories, and this Court should honor those boundaries. The unjust enrichment claims should be dismissed. *See Perry*, 324 F.3d at 851 (affirming dismissal of unjust enrichment claim); *City of Miami*, 800 F.3d at 1289 (same).

IV. THE TRIBES' STATE CLAIMS IMPERMISSIBLY SECOND-GUESS THE FDA AND ARE PREEMPTED

Yet more proof that the Tribes' suits are misguided is their effort to use the tort system to second-guess FDA policy choices. As noted above, the FDA heavily regulates pharmaceutical product marketing under authority granted by Congress. Pursuant to this authority and its careful weighing of the benefits and risks of prescription opioids, the FDA imposes a series of stringent

requirements on the Manufacturers' marketing of opioid medications. It is not the role of the Tribes, this Court, or a civil jury to second-guess determinations by the FDA.[12]

Under well-established rules of conflict preemption, if the Tribes' claims depend on an understanding of state law that imposes different requirements from those that federal law imposes, such that it would be impossible for the Manufacturers to comply with both federal *and* state law, those claims are preempted. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013). Because the Tribes' claims put the Manufacturers in precisely that untenable position, they are preempted. Specifically, all of the Tribes' state-law claims are preempted because they generally seek to impose liability for (i) the Manufacturers' marketing of opioids for the treatment of chronic pain, and (ii) their failure to include limitations on the dosage or duration of opioid treatment. And any surviving claims premised on alleged marketing misrepresentations are preempted *to the extent* the relevant representations are ones a pharmaceutical manufacturer could not alter without violating federal law. *See, e.g.*, *Suckow v. Medtronic, Inc.*, 971 F. Supp. 2d 1042, 1049 (D. Nev. 2013) ("*To the extent* that Plaintiffs' allegations contradict the FDA's conclusions . . . these claims are preempted." (emphasis added)); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 285 (E.D.N.Y. 2009) ("Plaintiff's breach of express warranty claim is preempted *to the extent* that it is premised on FDA approved representations made by the manufacturer." (emphasis added)); *Martin v. Medtronic, Inc.*, No. 1:15-CV-994, 2017 WL 825410, at *9 (E.D. Cal. Feb. 24, 2017) ("*To the extent* plaintiff challenges statements approved by the FDA . . . his fraud claim is . . . preempted . . . ." (emphasis added)).

[12] The manufacturers of generic opioids that have been sued by the Tribes in one or both of these cases also have filed separate motions to dismiss ("Generic Manufacturers' Motions") based upon the unique preemption arguments applicable to them.

"Federal law imposes [on drug manufacturers] . . . complex drug labeling requirements." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). In particular, "a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate"—a process that "involves costly and lengthy clinical testing." *Id.* Generally, once a product and associated warning labeling is approved, a manufacturer may not unilaterally alter the labeling without prior or subsequent FDA approval. *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b) (2008). And the term "labeling" includes not only the warning on the product's packaging, but all "brochures, booklets, mailings, catalogues, films, sound recordings, and literature" advertising it. *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013) (citing 21 C.F.R. § 202.1(*l*)(2)); *Del Valle v. PLIVA, Inc.*, No. 11-CV-113, 2011 WL 7168620, at *4 (S.D. Tex. Dec. 21, 2011) ("In essence, virtually all communication with medical professionals concerning a drug constitutes labeling."). Accordingly, just as pharmaceutical manufacturers cannot alter their product labeling without FDA approval, they also need FDA approval to alter any advertising of that product.

The reason pharmaceutical manufacturers cannot unilaterally add new warnings to their marketing materials is that the "FDA views overwarnings as problematic [since] they can render the warnings useless and discourage use of beneficial medications." *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1102 (10th Cir. 2017). Indeed, it is an "understandable, but mistaken, premise that a manufacturer's willingness to strengthen its warning is something always to be encouraged. Many would agree with that proposition, but the FDA doesn't." *Id.* Accordingly, although a brand-name manufacturer can "add or strengthen a contraindication, warning, [or] precaution . . . [or] add or strengthen an instruction about dosage and administration" if there is "newly acquired information" regarding a drug's risks, even then subsequent FDA approval is required and "the

FDA can reject [any] labeling changes" that a manufacturer proposes. 21 C.F.R. § 314.70(c)(6)(iii); *see Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 294-95 (6th Cir. 2015).

A brand-name manufacturer that markets its product with FDA-approved warnings cannot be held liable under state law for failing to issue *different* warnings *if* the FDA would have rejected those different warnings. *Wyeth v. Levine*, 555 U.S. 555, 571 (2009); *Cerveny*, 855 F.3d at 1098. In those circumstances, it would be impossible for the manufacturer to comply with both state and federal law. Accordingly, a "state tort claim is preempted if a pharmaceutical company presents clear evidence that the FDA would have rejected an effort to strengthen the label's warnings." *Cerveny*, 855 F.3d at 1098. And, because advertising is considered labeling, this reasoning applies directly to any false advertising, fraud, negligent misrepresentation, or other tort claims that are based on a manufacturer's allegedly inadequate disclosure of a drug's risks. *See Strayhorn*, 737 F.3d at 397 (holding that advertising and fraud claims are preempted because they "boil down to an alleged duty to provide additional information about [the product]"); *see also Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 479 (4th Cir. 2014) (holding that "negligent misrepresentations and fraudulent[] conceal[ment]" claims are preempted because they "are premised on the content of statements made by the defendant to the plaintiff").

Here, there is "clear evidence" that FDA would have precluded the Manufacturers from altering their labeling (and associated advertising) in the manner the Tribes' state-law claims would compel. *Cerveny*, 855 F.3d at 1098. Specifically, because the state-law claims seek to hold the Manufacturers liable for marketing opioids for the treatment of chronic non-cancer pain, and failing to limit the dose or duration of opioid treatments, they are preempted.

First, the FDA has approved almost all of the Manufacturers' opioid medications for the treatment of chronic pain, including chronic non-cancer pain. By definition, this approval means that the FDA has found that there is "substantial evidence that the drug will have the effect it purports or is represented to have" and that opioid medications are safe and effective for the treatment of chronic pain, including chronic non-cancer pain. 21 U.S.C. § 355(d). Critically, in response to a 2012 citizen petition (the "PROP Petition"), the FDA reviewed whether scientific evidence supported the use of opioids for the treatment of chronic pain, and concluded that it did. In 2013, the FDA responded to that petition by formally rejecting any distinction between cancer and non-cancer chronic pain: "It is FDA's view that a patient without cancer, like a patient with cancer, may suffer from chronic pain, and . . . FDA knows of no physiological or pharmacological basis upon which to differentiate the treatment of chronic pain in a cancer setting or patient from the treatment of chronic pain [generally]." FDA Response at 9. The FDA "therefore decline[d] to make a distinction between cancer and non-cancer chronic pain in opioid labeling." *Id.*

Because the FDA reviews a citizen petition under "the same standard [as] for manufacturer-initiated changes," the FDA's rejection of a citizen petition constitutes "clear evidence" that the FDA would have rejected a similar labelling change made by the manufacturer. *Cerveny*, 855 F.3d at 1103; *see also Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 385 (6th Cir. 2017) (clear evidence standard is met "where the FDA has rejected a proposed label modification in a submission to which the agency was responding"). Holding the Manufacturers liable for marketing their products for the treatment of chronic pain would in effect impose a categorical restriction on advertising opioid medication for an FDA-approved use. State laws that compel such a result are clearly preempted because they would "discourage use of beneficial medications." *Cerveny*, 855 F.3d at 1102. And while the Tribes might favor that result, "the FDA doesn't." *Id.*

Accordingly, federal law preempts the Tribes' claims premised on allegations that the Manufacturers should not have marketed their products for the treatment of chronic non-cancer pain.[13]

Second, the Tribes' state-law claims are also preempted to the extent that they seek to hold the Manufacturers liable for not placing limits on the dosage or duration of opioid treatments. The FDA has considered this issue and—in light of the importance of allowing doctors to individually assess each patient's needs—the FDA-approved indications for the Manufacturers' medications do not generally include limitations on the dose or duration of opioid treatments. FDA Response at 3. Indeed, in response to the same 2012 PROP Petition discussed above, the FDA expressly rejected a request to place any such categorical limits on the maximum dose or duration of treatment for patients receiving extended release opioids to manage their pain. *Id.* at 17. In rendering that opinion, the FDA emphasized that while recent scientific literature "underscore[s] the need for prescribers to evaluate carefully whether and under what circumstances to prescribe opioids (particularly in high doses) to patients with [certain] co-morbidities . . . [research does] *not* support PROP's argument that opioid labeling should include a maximum daily dose or a

[13] *See, e.g.*, Blackfeet 1AC ¶ 744 (seeking to hold a Defendant liable for the statement: "[i]t is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain"); *id.* ¶ 990 ("The Marketing Defendants breached their duty to Plaintiff by . . . aggressively promoting them for chronic pain for which they knew the drugs were not safe or suitable."); *id.* ¶ 991 ("The Marketing Defendants misrepresented and concealed . . . [opioids'] lack of suitability for chronic pain."); *id.* ¶ 1038 ("The Marketing Defendants . . . promoted them for chronic pain for which they knew the drugs were not safe or suitable."); *id.* ¶ 1054(h) (seeking to impose liability for "Marketing Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain . . . ."); *id.* ¶ 1112(g) (seeking to hold Defendants liable for "[c]laiming that opioids are an appropriate treatment for chronic pain"); Muscogee 1AC ¶ 405 (asserting that "Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain"); Muscogee 1AC ¶ 303 (accusing the Manufacturers of conspiring to promote opioids without "disclos[ing] publicly that the risks of using opioids for chronic pain outweighed their benefits and that the use of opioids for chronic pain was not supported by medically acceptable evidence").

maximum duration of use." *Id.* (emphasis added). And, as noted above, because the same standard applies to manufacturer-initiated changes, this rejection provides "clear evidence" that the FDA would have rejected a comparable labelling change proposed by the manufacturer. Accordingly, any claims premised on "misrepresentations" regarding maximum dosages or durations of treatment are also preempted by federal law.[14]

In short, because the FDA would have rejected an attempt by the Manufacturers to alter their advertising to express a categorical limitation on the use of opioid treatment for chronic, non-cancer pain, or express a limitation on the dose or duration of treatment, state law claims that would require such alterations are preempted.[15]

V. THE TRIBES' TORT CLAIMS FLOUT FUNDAMENTAL PROCEDURAL REQUIREMENTS

The Tribes claims also fail to comport with the basic procedural requirements that govern civil litigation. In pleading their claims, the Tribes have alleged fraud at every turn, and yet they fail to provide the details that Rule 9(b) requires of such allegations. At the same time, the Tribes' own pleadings *prove* that the vast majority of their claims are barred by the applicable statutes of

[14] *See, e.g.*, Blackfeet 1AC ¶ 44 (seeking to hold a Defendant liable for "creat[ing] the false perception that opioids were safe and effective for long-term use"); *id.* ¶ 147(f) (seeking to hold Defendants liable for promoting "[l]ong-term opioid use"); *id.* at 225 (alleging that it was wrongful for "Marketing Defendants [to tell] prescribers that they could safely increase a patient's dose to achieve pain relief"); *id.* ¶ 227 (seeking to hold Defendants' liable for claiming "there is 'no[] upward limit' for dosing" (alteration in original)); *id.* ¶ 231 (seeking to hold Defendants' liable for the statement "that opioids may be increased until 'you are on the right dose of medication for your pain,' at which point further dose increases would not be required"); *id.* ¶¶ 245-53 (seeking to hold Defendants liable for promoting long-term use); Muscogee 1AC ¶ 121 (seeking to hold a Manufacturer liable for stating "some patients 'need' a larger opioid dosage, regardless of the dose prescribed; (b) opioids have 'no ceiling dose' and are therefore the most appropriate treatment for severe pain; and (c) dosage escalations, even unlimited ones, are 'sometimes necessary.'").

[15] In addition, to the extent the Tribes seek to recover from the Manufacturers for alleged promotion of their medications' for "off-label" uses (*i.e.*, uses beyond those approved by FDA), these claims are also preempted. *See Summit* MTD § IV.A.

limitations. And the failure of all their substantive claims, for these and the other reasons discussed above, means that their civil conspiracy claims fail as well.

A. The Tribes Have Failed To Plead Their Fraud-Based Claims With Particularity

Under Rule 9(b), a party alleging fraud "must state with particularity the circumstances constituting [the] fraud." Because the rule is "cast in terms of the conduct alleged," it "is not limited to allegations styled or denominated as fraud or expressed in terms of the constituent elements of a fraud cause of action." *Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004). In other words, it applies to all allegations that "sound in fraud," regardless of their label. *Ind. State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 948 (6th Cir. 2009); *see also* 5A Charles Alan Wright et al., *Federal Practice and Procedure* § 1297 (3d ed., Westlaw 2018) ("Even when a plaintiff is not making a fraud claim, courts will require particularity in the pleading if the cause of action is premised on fraudulent conduct.").

Under each of their two theories of liability, the Tribes plead allegations sounding in fraud. *First*, the Tribes allege that the Manufacturers engaged in a sweeping scheme of intentional misrepresentation regarding the risks and benefits of their opioids. *See, e.g.*, Muscogee 1AC ¶ 358; Blackfeet 1AC ¶ 145. The Tribes allege that this "fraudulent marketing campaign" (Blackfeet 1AC ¶ 464) caused doctors to overprescribe the Manufacturers' opioids, thereby fueling the opioid crisis. *See* Muscogee 1AC ¶¶ 152-56, 350; Blackfeet 1AC ¶¶ 459-65. *Second*, the Tribes allege that the Manufacturers engaged in a fraudulent scheme to mislead state and federal regulators concerning the Manufacturers' purported failure to identify and report suspicious orders of opioids. *See* Muscogee 1AC ¶¶ 329-49; Blackfeet 1AC ¶¶ 799-827. In neither case, however, have the Tribes made these allegations of fraud with the requisite particularity. The Tribes' RICO, Lanham Act, common law fraud, negligent misrepresentation, and Montana Consumer Protection Act

claims—as well as the other state-law claims that rely on those allegations—should therefore be dismissed. *See also Summit* MTD § II.B.4.b (advancing similar arguments).

1. The Tribes' Fraudulent Marketing Allegations Fail To Identify Any Doctors Who Heard The Misrepresentations Or Issued Prescriptions Because Of The Misrepresentations

"The point of Civil Rule 9(b) is to prevent . . . casual allegations of fraud." *United States ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 882 (6th Cir. 2017). "[I]nferences and implications" will not satisfy the rule—"[i]t demands specifics." *Id.* at 881. A plaintiff must "allege the time, place, and content of the alleged misrepresentations on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Farnsworth v. Nationstar Mortg., LLC*, 569 F. App'x 421, 430 (6th Cir. 2014). The plaintiff must also "explain with particularity" the reliance induced by the alleged misrepresentation. *Evans v. Pearson Enters., Inc.*, 434 F.3d 839, 852-53 (6th Cir. 2006) (rejecting "[c]onclusory statements of reliance"); *see Anderson*, 407 P.3d at 699 (actual, justifiable reliance is an element of Montana fraud and negligent misrepresentation).

The Tribes' allegations of fraudulent marketing fail to provide the "specifics" that Rule 9(b) "demands." *Walgreen*, 846 F.3d at 881. They have completely failed to identify *any* doctor—much less one with any connection to the Tribes—who heard those allegedly false statements. Likewise, they have failed to identify *any* doctor who prescribed an opioid *because of* those false statements. In other words, the Tribes have failed to allege *any* specifics linking the alleged misconduct (*i.e.*, the misstatements) to the alleged harm (*i.e.*, expenses incurred by the Tribe *as a result of* the misstatements).

The Sixth Circuit's decision in *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496 (6th Cir. 2008), makes clear that this pleading deficiency requires dismissal. In that False Claims Act case, the relator claimed that Ford had "fraudulently induced the federal government

to contract with [it] by inflating, in official reports to the government, the extent of [its] dealings with small and minority-owned businesses." *Id.* at 499. The Sixth Circuit held that the relator's complaint "identified allegedly false or fraudulent statements made by Ford with sufficient particularity" to satisfy Rule 9(b). *Id.* at 505. But that was not enough. The relator also needed to provide details concerning "Ford's claim for payment from the federal government, *and the manner in which the false statements induced the government to make a claimed payment to Ford*." *Id.* (emphasis added). Because the relator failed to identify even one example of a claim that was paid because of Ford's false statements, the court affirmed the dismissal of the complaint. *Id.* at 506.

Applying the same reasoning, many federal courts addressing allegations of pharmaceutical fraud have recognized that Rule 9(b) requires plaintiffs to identify particular doctors who were exposed to the misrepresentations and issued prescriptions *because of* those misrepresentations. Directly on point, for instance, is *City of Chicago v. Purdue Pharma L.P.*, No. 14-CV-4361, 2015 WL 2208423 (N.D. Ill. May 8, 2015). There, Chicago alleged the same fraudulent scheme of opioid marketing that the Tribes plead here. *See id.* at *1-4. And the court concluded that almost all of the city's claims failed under Rule 9(b) because, like the Tribes, the city failed to identify any Chicago-area doctors who had heard the misrepresentations—much less one who had issued opioid prescriptions as a result of the misrepresentations. *See, e.g.*, *id.* at *10 ("What the City does not allege, however, is the name of any Chicago doctor or consumer to whom any Actavis entity made an alleged misrepresentation . . . .").

The Third Circuit reached the same result in *Travelers Indemnity Co. v. Cephalon, Inc.*, 620 F. App'x 82 (3d Cir. 2015). There, an insurer alleged that Cephalon's fraudulent marketing of certain opioids had caused the insurer to pay for millions of dollars' worth of inappropriate

prescriptions. *Id.* at 84. The Third Circuit held that the insurer's allegations were insufficient under Rule 9(b) because they "fail[ed] to identify any specific fraudulent statements, omissions, or misrepresentations that were made to doctors who prescribed" the drugs. *Id.* at 86. Because the insurer failed to specify, among other things, "*to whom* any sales pitch was made," the court concluded that its "claims sounding in fraud cannot stand." *Id.* (emphasis added).[16]

A plaintiff cannot "avoid the specificity requirements of Rule 9(b) by relying upon the complexity of the edifice which he created." *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 564 (6th Cir. 2003). "If the complaint alleges a complex and far-reaching fraudulent scheme, then that scheme must be pleaded with particularity and the complaint must also provide examples of specific fraudulent conduct that are representative samples of the scheme." *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 830 (6th Cir. 2018). The Tribes fail to meet this standard. To provide adequate "representative samples," the Tribes needed to identify specific instances of doctors' receiving, and issuing prescriptions to Tribe members based on, alleged misrepresentations from each of the named Manufacturers. *See City of Chicago*, 2015 WL 2208423, at *10-12 (examining allegations as to each Manufacturer defendant). The Tribes have come nowhere close. They have not identified a single doctor who received the

[16] *See also In re Bextra & Celebrex Marketing Sales Practices & Product Liability Litigation*, No. 05-CV-01699, 2012 WL 3154957, at *6 (N.D. Cal. Aug. 2, 2012) (requiring "*specific* allegations that individual physicians actually relied on these misrepresentations in writing the challenged prescriptions. . . . A conclusory statement that '[the insurer], physicians, and patients relied on Defendants' deceptive trade practices' will not suffice without further factual context"); *Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.*, Civil Action No. 09-3418 (MLC), 2010 WL 1257790, at *4 (D.N.J. Mar. 29, 2010) (dismissing for failure to plead any instance in which plaintiffs or their doctors "received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe one of the Subject Drugs to Plaintiffs"); *In re Actimmune Mktg. Litig.*, No. 08-CV-02376 MHP, 2009 WL 3740648, at *11 (N.D. Cal. Nov. 6, 2009) ("Neither individual alleges with any degree of specificity that they or their doctors ever were actually the recipient of any of defendants' fraudulent representations."), *aff'd*, 464 F. App'x 651 (9th Cir. 2011).

Manufacturers' alleged misrepresentations and who issued a prescription to a Tribe member *because of* those misrepresentations. (In fact, the Tribes have not identified a single doctor who received the Manufacturers' alleged misrepresentations—period.) Because the Tribes cannot identify with specificity "even one" particular instance of fraud—much less the representative samples necessary to implicate *all* of the Manufacturers—their allegations fail to satisfy Rule 9(b). *See Walgreen*, 846 F.3d at 882.

This pleading failure is not a mere technicality. There is good reason to think the Tribes cannot identify any actionable prescriptions resulting from the Manufacturers' supposed misrepresentations. Indeed, for Manufacturers that sell generic medicines, there is no promotion of those medicines.[17] Moreover, as discussed above, and as the Tribes acknowledge, the risks of opioids have long been known to doctors. The Manufacturers' opioid medications have at all times borne FDA warnings prominently highlighting the risks of abuse, addiction, and even death. And since July 2012, many opioids have been subject to FDA-approved Risk Evaluation and Mitigation Strategies intended to "reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse" by educating prescribers about the risks and benefits of opioids. FDA Response at 4. Common sense therefore suggests that even if doctors were exposed to the alleged misrepresentations, their prescribing decisions would not have been impacted. *See Sidney Hillman*, 873 F.3d at 577 ("[S]ome physicians doubtless were proof against the campaign of

[17] The Generic Manufacturers' Motions further explain the absence of any allegations of false marketing as to them, given that, as numerous courts have recognized, "[g]eneric products are typically not marketed to physicians or patients" because "the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete." *New York v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

disinformation."); *cf. Iqbal*, 556 U.S. at 679 (courts should draw on "judicial experience and common sense" in determining whether a claim is plausible).

Moreover, the Tribes must plead examples of doctors' relying on alleged *misrepresentations*—not the Manufacturers' truthful marketing, which is protected by the First Amendment and cannot form the basis for liability under any of the Tribes' legal theories. *See, e.g., United States v. Caronia*, 703 F.3d 149, 164-65 (2d Cir. 2012) (recognizing principle in context of off-label promotion). And these doctors must have prescribed opioids to tribal members who reside within the Tribe's sovereign territory. Given the real possibility that no such actionable prescriptions exist, the Tribes should be required to identify at least *some* specific instances where alleged misrepresentations had at least this first causal connection to the Tribes' alleged injuries.

The need for concrete details is especially pressing because of the extraordinary degree to which the Tribes indiscriminately lump together the various Manufacturers (and all of the Defendants, in fact). The Sixth Circuit has repeatedly held that this kind of group pleading—where a plaintiff relies on "general averments of fraud attributed to 'the defendants'" as a whole—is impermissible. *Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992); *see also Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 551 (6th Cir. 2012) (fraud claim fails under Rule 9(b) because it "fail[ed] to allege the speaker of the alleged statements, instead referring vaguely only to 'defendants,' of which there are many in this case"). Yet the Tribes do just that, treating the various Manufacturers as if they were interchangeable, even though there can be no dispute that the Manufacturers sold different opioid products (*e.g.*, generic vs. brand medicines, long-acting opioids vs. short-acting opioids), some Manufacturers did not promote those products at all, and, for those that did, each Manufacturer did so differently and often to different audiences at different times and places. Indeed, the Blackfeet Tribe concedes that "not every Marketing

Defendant propagated . . . each misrepresentation." Blackfeet 1AC ¶ 149. In view of that admission, it is critical that the Tribes provide specific examples that identify *whose* alleged misrepresentations have been heard by doctors who, as a result, prescribed opioids to Tribe members within their territory.

The Tribes' failure to allege the supposed scheme of fraudulent marketing with particularity requires dismissal of both Tribes' first RICO claim, the Blackfeet Tribe's common law fraud, negligent misrepresentation, and MCPA claims, and the Muscogee Nation's Lanham Act claim. *See Paatalo v. First Am. Title Co. of Mont., Inc.*, No. 13-CV-128, 2014 WL 2002839, at *4-5 (D. Mont. May 14, 2014) (applying Rule 9(b) to Montana fraud and negligent misrepresentation claims); *PNC Bank, Nat'l Ass'n v. Wilson*, No. 14-CV-80, 2015 WL 3887602, at *7 (D. Mont. June 23, 2015) (applying Rule 9(b) to MCPA claims); *Bobbleheads.com, LLC v. Wright Bros., Inc.*, 259 F. Supp. 3d 1087, 1095 (S.D. Cal. 2017) ("Rule 9(b) applies to Lanham Act claims that are grounded in fraud."). It also requires dismissal of the Tribes' public nuisance, negligence, and unjust enrichment claims to the extent that they rest on allegations of fraudulent marketing—which they all do to a considerable degree. *See, e.g.*, Muscogee 1AC ¶¶ 423, 438, 486; Blackfeet 1AC ¶¶ 892, 935-36, 989-91, 1090; *see also In re Westinghouse Sec. Litig.*, 90 F.3d 696, 717 n.21 (3d Cir. 1996) (count sounded in fraud where "it incorporated all prior factual allegations, including those alleging intentional, knowing, and reckless conduct").

2. The Tribes Fail To Allege With Particularity Any Instances Of Fraud Underlying The Supposed "Supply Chain Enterprise"

Both Tribes' second RICO claims allege that the Manufacturers participated in a "Supply Chain Enterprise" that engaged in "a scheme to defraud federal and state regulators" with respect to the Manufacturers' monitoring and reporting obligations. Blackfeet 1AC ¶ 861; *accord* Muscogee 1AC ¶ 344. The Tribes allege predicate acts of racketeering consisting of mail fraud,

wire fraud, and violations of a provision of the CSA, 21 U.S.C. § 843(a)(4), that prohibits knowingly or intentionally "furnish[ing] false or fraudulent material information in, or omit[ting] any material information from" records required to be made or kept under the CSA. *See* Muscogee 1AC ¶ 392; Blackfeet 1AC ¶ 866. In addition to the numerous other failings explained in *Summit*, the Tribes have failed to allege any of these predicate acts with particularity.

Mail and Wire Fraud: The Sixth Circuit has repeatedly held that, under RICO, "predicate acts of mail or wire fraud must be pled with particularity pursuant to Rule 9(b)." *Grubbs v. Sheakley Grp., Inc.*, 807 F.3d 785, 804 n.5 (6th Cir. 2015). "When pleading predicate acts of mail or wire fraud, in order to satisfy the heightened pleading requirements of Rule 9(b), a plaintiff must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 404 (6th Cir. 2012).

Nowhere in their allegations concerning the Supply Chain Enterprise do the Tribes allege any predicate acts of mail or wire fraud with this necessary level of detail. *See* Muscogee 1AC ¶¶ 329-52, 380-408; Blackfeet 1AC ¶¶ 799-827, 856-87. Indeed, both Tribes admit as much, claiming (incorrectly) that "[m]any" of the details "have been deliberately hidden by Defendants." Muscogee 1AC ¶ 345; Blackfeet 1AC ¶ 876.[18] But even if "[m]any" of the details were hidden from the Tribes (a dubious assertion in its own right), that does not excuse the Tribes' failure to plead at least one instance of predicate fraud with particularity. As the Sixth Circuit explained in *Walgreen*, courts have "no more authority to 'relax' the pleading standard established by Civil

[18] In the same paragraph in which it makes this admission, the Muscogee Nation also claims that "in some instances" it has provided the necessary details. Muscogee 1AC ¶ 345. Tellingly, it provides no cross-reference to any other part of its complaint. *See id.*

Rule 9(b) than [they] do to increase it." 846 F.3d at 881. If a plaintiff lacks personal knowledge of even a single instance of fraud, it is "not the right plaintiff." *Id.* at 882.

Furnishing False Information (21 U.S.C. § 843): An allegation that a RICO defendant violated 21 U.S.C. § 843(a)(4) sounds in fraud and therefore should be subject to Rule 9(b). But even under the Rule 8 standard, the Tribes' allegations concerning this purported predicate offense fall woefully short.[19] The Blackfeet Tribe merely asserts, in conclusory fashion, that the Manufacturers "were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports." Blackfeet 1AC ¶ 809. The complaint fails to provide even a single instance of this alleged knowing failure to report material information. And the Muscogee complaint is even worse: it contains only the bare allegation that "[t]he Defendants violated 21 U.S.C. § 843(a)(4) by knowingly and intentionally furnishing false information in, and omitting material information from, reports, records, and other documents required to be made, kept, and filed under the relevant subchapter of Title 21 of the United States Code." Muscogee 1AC ¶ 388. That "recital[] of the elements of a cause of action, supported by [a] mere conclusory statement[]" plainly "do[es] not suffice" to state a claim. *Iqbal*, 556 U.S. at 678.

* * *

The Tribes will no doubt point to the sheer length of their complaints as evidence that they have complied with Rule 9(b). But an "unwieldy, everything-but-the-kitchen-sink approach to pleading" does not guarantee that a plaintiff has satisfied his burden. *Lawrie v. Ginn Dev. Co.*, 656 F. App'x 464, 465, 473 (11th Cir. 2016) (per curiam) (dismissing complaint despite its

[19] Moreover, as explained in *Summit*, an alleged failure to comply with DEA monitoring and reporting requirements cannot serve as a predicate act. *See Summit* MTD § III.B.4; *Summit* Reply § V.B.2.a.

"impressive magnitude"). "Rule 9(b) does not permit [the Court] to assemble the [Tribes'] impressive collection of disparate and disjointed facts into a collage of fraud." *Id.* at 474. It demands that they actually plead the details of specific misrepresentations—including who heard and relied on them. The Tribes have failed to do so.

B. The Vast Majority Of The Tribes' Claims Are Time-Barred

The Court may grant a motion to dismiss when it is clear from the face of the complaints that some or all of a plaintiff's claims are untimely. *See, e.g.*, *Cataldo*, 676 F.3d at 547; *see also Jones v. Bock*, 549 U.S. 199, 215 (2007). Once the Manufacturers have established that the statute of limitations has run, "then the burden shifts to the [Tribes] to establish an exception to the statute of limitations." *Campbell v. Grand Trunk W. R.R. Co.*, 238 F.3d 772, 775 (6th Cir. 2001); *see also Reid v. Baker*, 499 F. App'x 520, 524-26 (6th Cir. 2012). The vast majority of the Tribes' claims are facially time-barred.

The Tribes were required to bring their claims within two to four years of the date on which the cause of action accrued, depending on the particular claim at issue. Yet the Tribes rest on alleged false marketing statements made by the Manufacturers years—and in some cases decades—ago. *See* Addendum B (summarizing alleged misrepresentations). And the Tribes knew or, with the exercise of reasonable diligence, should have known of their claims at least four years before they filed these suits on April 3, 2018 (Muscogee Nation) and June 26, 2018 (Blackfeet Tribe). Specifically, the Tribes' allegations make clear that they allegedly incurred an injury well before the statutory periods. As such, the following Muscogee Nation claims are time-barred to the extent they are based on misrepresentations or other alleged misconduct that occurred before the listed date:

- April 3, 2016: Negligence and negligence per se, unjust enrichment, civil conspiracy, and nuisance (for damages)

- April 3, 2015: Lanham Act
- April 3, 2014: RICO

Likewise, the Blackfeet Tribe's claims are time-barred to the extent they are based on misrepresentations or other alleged misconduct that occurred before the listed date:

- June 26, 2016: Common law fraud, civil conspiracy based on fraud, and violation of the Montana Unfair Trade Practices and Consumer Protection Act
- June 26, 2015: Negligence and negligent misrepresentation, unjust enrichment, civil conspiracy (other than based on fraud), and nuisance (for damages)
- June 26, 2014: RICO

Because this is all apparent on the face of the Tribes' complaints, this Court should dismiss all of the aforementioned claims.

1. The Tribes' Claims Are Governed By Two- To Four-Year Statutes Of Limitations

All of the Tribes' state-law claims are subject to statutes of limitations of between two and three years.[20] Under both Oklahoma and Montana law, the statutes of limitations begin to run

[20] The Muscogee Nation's state law claims for negligence and negligence per se, unjust enrichment, civil conspiracy, and nuisance (for damages) have a two-year statute of limitations. *See* Okla. Stat. tit. 12, § 95(A)(3); *see also Christ's Legacy Church v. Trinity Grp. Architects, Inc.*, 417 P.3d 1223, 1228 (Okla. Civ. App. 2018) (negligence claim); *City of Tulsa*, 280 P.3d at 320-21 (unjust enrichment claim); *West v. Jane Phillips Mem'l Med. Ctr.*, 404 P.3d 896, 904 (Okla. Civ. App. 2017) (civil conspiracy claim); *Branch v. Mobil Oil Corp.*, 788 F. Supp. 531, 536 (W.D. Okla. 1991) (nuisance claim for damages). The Blackfeet Tribe's claims for common law fraud, civil conspiracy based on fraud, and violation of the Montana Unfair Trade Practices and Consumer Protection Act are also governed by two-year statutes of limitations. Mont. Code Ann. § 27-2-203 (fraud-based claims); *id.* § 27-2-211(1) (unfair trade practices act claims); *see also Osterman v. Sears, Roebuck & Co.*, 80 P.3d 435, 440, 441, 442 (Mont. 2003) (fraud and unfair trade practices act claims); *Lence Family Tr. v. Christensen*, 623 F. App'x 314, 315 (9th Cir. 2015) (fraud claim). The Blackfeet Tribe's state law claims for negligence and negligent misrepresentation, unjust enrichment, civil conspiracy (other than based on fraud), and nuisance (for damages) are subject to a three-year statute of limitations. *Id.* §§ 27-2-204(1), 27-2-202(3); *see also Lundgren v. Eastern Mont. Comty. Mental Health Ctr.*, 1998 MT 88N, ¶ 29, 1998 WL 208152, at *6 (Mont. Apr. 23, 1998) (negligence claim); *Grizzly Sec. Armored Express, Inc. v. Bancard Servs., Inc.*, 384 P.3d 68, 73-74 (Mont. 2016) (unjust enrichment claim); *Lence Family*

when all of the elements of a cause of action have occurred. *Kirby v. Jean's Plumbing Heat & Air*, 222 P.3d 21, 26 (Okla. 2009); Mont. Code Ann. § 27-2-102(1)(a); *see also* Mont. Code Ann. § 27-2-102(2).

Although both states also apply some version of the discovery rule, that rule does not prevent the running of the limitations periods here. In Oklahoma, the rule suspends the running of the limitations period "until the injured party knows or, *in the exercise of reasonable diligence*, should have known of the injury." *Calvert v. Swinford*, 382 P.3d 1028, 1033 (Okla. 2016) (emphasis added). The discovery rule can be applied only "when doing so would not offend the purpose of the rule," which is "to exclude the period of time during which the injured party is reasonably unaware that an injury has been sustained." *Id.* Under Montana law, the discovery rule is even more limited. As a general rule, "[l]ack of knowledge of the claim or cause of action, or of its accrual, by the party to whom it has accrued does not postpone the beginning of the period of limitation." Mont. Code Ann. § 27-2-102(2). But if the facts constituting the claim are concealed or self-concealing, or if the defendant has acted to prevent discovery of the facts, then the statute of limitations does not begin to run "until the facts constituting the claim have been discovered or, *in the exercise of due diligence*, should have been discovered by the injured party." Mont. Code Ann. § 27-2-102(3) (emphasis added); *see also Osterman*, 80 P.3d at 441; *Christian v. Atl. Richfield Co.*, 358 P.3d 131, 156 (Mont. 2015) (same).

Tr., 623 F. App'x at 315 (civil conspiracy claim); *Town of Superior v. Asarco, Inc.*, 874 F. Supp. 2d 937, 945-46 (D. Mont. 2004) (nuisance claim for damages). If the Court does not dismiss the Blackfeet Tribe's federal common law public nuisance claim for failure to state a claim (*see supra* § III.A.2), it should apply a three-year state statute of limitations to that claim as well. *See Wilson v. Garcia*, 471 U.S. 261, 266-67 (1985) ("When Congress has not established a time limitation for a federal cause of action, the settled practice has been to adopt a local time limitation as federal law if it is not inconsistent with federal law or policy to do so."); *see also Cent. States Se. & Sw. Areas Pension Fund v. Kraftco, Inc.*, 799 F.2d 1098, 1104 (6th Cir. 1986).

As for the federal law claims, a four-year limitations period applies to the Tribes' civil RICO claims. *Rotella v. Wood*, 528 U.S. 549, 552, 553-54 (2000); *see also Hood v. United States Postal Serv.*, Nos. 17-1048/1050/1052, 2017 WL 6988055, at *2-3 (6th Cir. Oct. 11, 2017). The limitations period for RICO begins to run when the plaintiff knows or should know of an injury—regardless of whether the plaintiff has discovered the pattern of RICO activity. *Rotella*, 528 U.S. at 552-54; *see also Hood*, 2017 WL 6988055, at *2-3.

Although the Lanham Act does not contain its own statute of limitations, a strong presumption exists that the Muscogee Nation's claim is barred under principles of laches if the analogous state statute of limitations has lapsed. *Herman Miller, Inc. v. Palazzetti Imps. & Exps., Inc.*, 270 F.3d 298, 320-22 (6th Cir. 2001).[21] Here, the analogous state statute is Okla. Stat. tit. 12, § 95(A)(2), which provides a three-year limitations period for unfair and deceptive trade practices claims. *See West v. Jane Phillips Mem'l Med. Ctr.*, 404 P.3d 896, 904 (Okla. Civ. App. 2017).

2. The Tribes Knew, Or Should Have Known, Of The Vast Majority Of Their Claims Many Years Before They Filed Their Lawsuits

The Tribes knew, or through the exercise of due diligence should have known, of practically all of their claims more than four years before they filed their respective lawsuits. Indeed, the complaints themselves make two points abundantly clear: (1) almost all of the alleged misconduct occurred and began causing the alleged injury years or even decades before the Tribes initiated these lawsuits, and (2) an abundance of public information was available to the Tribes to

[21] Application of laches also requires lack of diligence by the party against whom the defense is asserted and prejudice to the party asserting the defense. *Herman Miller, Inc.*, 270 F.3d at 320-22. For the reasons discussed below, the Nation knew about this claim, or should have known with the exercise of reasonable diligence, many years before it filed suit. And the Manufacturers would suffer prejudice if this Court were to excuse the Nation's delay; it would face exposure to greater damages that reach back years, if not decades, in time and that are significantly harder to evaluate or challenge for that reason. *See id.* at 322 (prejudice found where potential delay in bringing suit increased "potential liability for damages.").

put them on notice of their alleged claims. These two points—based on the Tribes' own pleadings—establish that the Tribes' claims are time-barred as a matter of law.

a. *The Tribes' Claims Are Premised On Alleged Conduct That Happened Many Years Ago*

In bringing claims based on alleged fraudulent marketing, the Tribes rely almost entirely on alleged misrepresentations that occurred and began causing the alleged injury in the 1990s and early 2000s. *See* Addendum B. The Blackfeet Tribe alleges, for example, that Purdue issued a press release stating that the fear of opioids was exaggerated in 1996 and provided inaccurate testimony to Congress in 2001. Blackfeet 1AC ¶¶ 160-61; *see also id.* ¶¶ 170, 227, 271. The Muscogee Nation likewise alleges that Purdue issued misleading marketing materials in 1996 and sponsored misleading training sessions in "the late 1990s and early 2000s," and that a doctor connected to the Manufacturers made unsubstantiated claims in 1986 and 1996. Muscogee 1AC ¶¶ 106, 110, 128. The Blackfeet Tribe likewise alleges that Cephalon, Endo, and Purdue each sponsored a misleading article on opioids in 2007. *See* Blackfeet 1AC ¶ 212. Indeed, even a cursory review of the "examples" of misstatements alleged by the Tribes makes clear that *only a handful* are even alleged to have been made in or after 2014. *See* Addendum B. In short, with few exceptions, the Tribes' claims are based on misrepresentations that were made and began causing the alleged injury well before the applicable two- to four-year statutory limitations periods.

b. *The Tribes Knew Or Should Have Known Of Their Claims Many Years Ago*

The Tribes knew or, at least, should have known of their claims many years before they filed these lawsuits—and that is abundantly clear from the face of the complaints. *See Cooey v. Strickland*, 479 F.3d 412, 422, 424 (6th Cir. 2007) (dismissing complaint as time-barred because plaintiff knew or should have known of claim before statutory period); *Bloedow v. CSX Transp., Inc.*, 638 F. Supp. 2d 831, 838-39 (N.D. Ohio 2009) (same). Specifically, the Tribes can be

charged with knowledge for at least two reasons: (1) the Tribes' pleadings rely heavily on public documents that themselves establish that the Tribes should have known of their claims many years before they chose to file suit, and (2) the City of Chicago and a pair of California counties filed substantially similar lawsuits in mid-2014.

First, the Tribes' pleadings establish on their face that the Tribes knew or, with the exercise of reasonable diligence, should have known of their claims many years before the Tribes filed suit. The complaints are replete with citations, references, websites, articles, and other sources and statements clearly establishing that the Tribes had access to more than enough information to put a diligent plaintiff on notice of its alleged claims.

For example, both Tribes allege that the FDA warned the public of the risks of opioids years before the two- to four-year statutory periods applicable here. The Blackfeet Tribe alleges that "[o]n July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from" certain opioid medications. Blackfeet 1AC ¶ 739. The Tribe further alleges that "[o]n September 27, 2007, the FDA issued a public health advisory to address numerous reports" regarding "death or life-threatening side effects" from the use of opioids. *Id.* ¶ 742. Both Tribes also rely on the FDA's September 10, 2013 response to the PROP Petition to try to establish the serious risks of opioids. The Muscogee Nation, for example, relies on that response letter to allege that, *in 2013*, the FDA found that "(1) 'most opioid drugs have "high potential for abuse"; (2) treatment of chronic pain with opioids poses 'known serious risks,' including 'addiction, abuse, and misuse . . . overdose and death' even when used 'at recommended doses'; and (3) opioids should be used only 'in patients for whom alternative treatment options' have failed." Muscogee 1AC ¶ 113 & n.32 (alteration in original); *see also id.* ¶ 124 & n.46 (relying on same to support allegation that "[t]he FDA has stated that the available data 'suggest a relationship between

increasing opioid dosages and risk of certain adverse events'"); Blackfeet 1AC ¶ 255 (relying on same to plead that hyperalgesia is a "known serious risk").

Both Tribes also discuss, at great length, a series of public investigations and settlements—all more than four years before these lawsuits—that also put the Tribes on notice of their claims. For example, the Blackfeet Tribe alleges that "[o]n September 29, 2008, Cephalon . . . agreed to pay $425 million in civil and criminal penalties," and that the agreement was announced in a "DOJ press release." Blackfeet Tribe 1AC ¶ 740. The Tribe also alleges that, in May 2007, "Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin" and that the company "was ordered to pay $600 million in fines and fees." *Id.* ¶ 745. The Tribe likewise relies on a 2003 Wall Street Journal article to allege that the FDA "admonished" Purdue in 2003 regarding the risk of death from OxyContin. *Id.* ¶ 240 & n.75; *see also* Muscogee 1AC ¶ 139 & nn.63-64 (relying on a plea agreement and a publicly-available Law360 article to allege that, in 2007, Purdue "settled federal allegations that it had introduced misbranded drugs into interstate commerce," "paid over $700 million," and admitted that some employees made statements about OxyContin "'that were inconsistent with the FDA-approved prescribing information….'"); *id.* ¶¶ 214, 215, 219, 253. And the Tribe pleads a series of other federal actions that would have readily revealed the basis for their claims in 2007, 2008, and 2012. Blackfeet 1AC ¶ 750.

Moreover, the Tribes refer to and rely on scores of older articles and statements which, they allege, disclosed the risks of opioids. The Blackfeet Tribe, for example, cites one article found on the public website of a medical association in 2009 to allege that opioid users "are unable to function normally," and another from a 2008 medical journal allegedly demonstrating "that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work." Blackfeet 1AC ¶ 253 & nn.82-83. The Tribe also alleges that a

"respected leader in the field of pain treatment" who was "highly influential" in promoting opioids during the 1980s and 1990s publicly admitted in 2003, 2011, and 2012 that his teachings on pain management during the preceding decades were inaccurate. *Id.* ¶¶ 374, 377 & nn.153-54, 378 n.155, 379 n.156. In discussing the opioid crisis in Montana, the Tribe points to a "2007 study" that "found 'a very strong correlation between therapeutic exposure to opioid analgesics, as measured by their prescriptions filled, and their abuse." *Id.* ¶ 662.[22] And the Muscogee Nation likewise alleges that a doctor who was the "most prominent [Key Opinion Leader]" made unsubstantiated claims *in 1986 and 1996* about opioids, but publicly admitted his error *six years ago in 2012*. Muscogee 1AC ¶ 128. The Nation also cites a 2011 CDC report to allege that "overdose deaths from prescription opioids had reached 'epidemic levels'" *seven years ago*. Muscogee 1AC ¶ 267 & n.133.

These are just a few examples of the facts pleaded throughout the Tribes' complaints establishing that the Tribes at the very least should have known of their claims more than four (let alone two or three) years before they filed suit. *See also*, *e.g.*, Blackfeet 1AC ¶¶ 118 n.17 (2003), 126 n.24 (2003); 255 n.86 (2001), 255 n.88 (2012), 296 (2012), 314 n.114 (2010), 377 nn.152-54 (2012), 387 n.158, 392 n.165 (2011), 394 n.166 (2012), 407 n.170 (2011), 466 n.188 (2007), 662 (2007); Muscogee 1AC ¶¶ 6 n.4 (2010), 13 n.9 (2013), 17 n.12 (2014), 19 n.15 (2013), 113 n.32 (2013), 113 n.33 (2009), 124 n.46 (2013), 136 n.61 (2002), 264 n.126 (2010), 266 n.130 (2013),

[22] The Blackfeet Tribe also alleges that the CDC declared the opioid crisis a "'public health epidemic'" as of April 29, 2014, and that the "U.S. Surgeon General has deemed" the opioid crisis "an 'urgent health crisis'" as of that date. Blackfeet 1AC ¶ 17 & n.6; *see also id.* ¶¶ 18 n.7 (referring to statement of the CDC director in 2014), 250 n.77 (noting FDA warning letters "were available to Defendants on the FDA website"). Like its amended complaint, the Blackfeet Tribe's original complaint alleged a host of publicly available facts before the applicable statutory periods further establishing that the Blackfeet Tribe's claims are time-barred now. *See*, *e.g.*, *id.* ¶¶ 253 n.83, 255 nn.86, 88, 377 nn.152-53, 387 n.158, 392 n.165, 407 n.170, 466 n.188.

267 n.133 (2011). The Tribes cannot rely on these allegations to support their affirmative claims and, at the same time, allege they somehow reasonably remained in the dark when all of this information was in the public domain. Any reasonably diligent investigation would have discovered the precise information now alleged in the Tribes' complaints. As a result, their own allegations establish—as a matter of law—that their claims are time-barred.

Second, at least two governmental entities filed substantially similar lawsuits years ago. The City of Chicago sued many of the same Manufacturers for the same conduct on June 2, 2014, and, following removal, filed its complaint in federal court on July 17, 2014. *See City of Chicago v. Purdue Pharma L.P.*, No. 14-CV-4361, 2014 WL 5157685, at *2 (N.D. Ill. Oct. 10, 2014); *see also City of Chicago* Complaint (filed July 17, 2014), ECF No. 76 (with limited redactions); *City of Chicago* Complaint (filed July 22, 2014), ECF No. 81-1 (fully unredacted). Similarly, Santa Clara and Orange Counties filed a substantially similar lawsuit on May 21, 2014. *See People acting by and through Santa Clara Cty. Counsel & Orange Cty. Dist. Att'y v. Purdue Pharma L.P., et al.*, No. 30-2014-00725287-CU-BN-CXC (Cal. Super. Ct. filed May 21, 2014). Those lawsuits received ample media attention and were themselves more than sufficient to put the Tribes on notice of their claims. *See, e.g., Reaves v. Cable One, Inc.*, No. 1:11-cv-03859, 2015 WL 12747944, at *3 (N.D. Ala. Mar. 16, 2015) ("The filing of [prior case] establishes that reasonably diligent plaintiffs would have discovered . . . the facts regarding [defendant's] alleged" conduct.); *In re Wells Fargo Mortg.-Backed Certificates Litig.*, No. 09-CV-13756, 2010 WL 4117477, at *6-7 (N.D. Cal. Oct. 19, 2010) (same); *cf. Thieltges v. Royal Alliance Assocs., Inc.*, 334 P.3d 382, 386 (Mont. 2014) ("Appellants could readily have discovered [the relevant facts] through public records . . . ."). The Chicago and Santa Clara lawsuits *alone* establish that the Tribes knew or should have known of their claims no later than mid-2014.

C. The Civil Conspiracy Claims Fail

The various flaws in the Tribes' substantive claims also doom their attempt to link all of the Manufacturers together as part of a civil conspiracy. Under both Montana and Oklahoma law, civil conspiracy does not create independent liability. *Gaylord Entm't Co. v. Thompson*, 958 P.2d 128, 148 (Okla. 1998) ("[C]ivil conspiracy itself does not create liability."); *Duffy v. Butte Teachers' Union, No. 332*, 541 P.2d 1199, 1202 (Mont. 1975) (same). Rather, a civil conspiracy claim is entirely derivative and turns on the existence of an underlying tort. *Brock v. Thompson*, 948 P.2d 279, 294 (Okla. 1997); *Mary J. Baker Revocable Tr. v. Cenex Harvest States Coops.*, No. DV-0306, 2004 Mont. Dist. LEXIS 3149, at *30 (Mont. Dist. Ct. 2004), *aff'd*, 207 MT 159. Because the Tribes have failed to state a claim for any underlying tort, their civil conspiracy claims likewise fail.

Moreover, any civil conspiracy claims premised on underlying negligent conduct should be dismissed for an additional reason. Civil conspiracy requires the Manufacturers to have *intentionally or knowingly* entered into an agreement to accomplish an unlawful act; there is no such thing as a *negligent* conspiracy. *See, e.g.*, *Ruth v. A.O. Smith Corp.*, No. 1:04-CV-18912, 2005 WL 2978694, at *3 (N.D. Ohio Oct. 11, 2005) ("[T]he great majority of jurisdictions agree that conspiracy claims cannot be founded on the tort of negligence. This conformity exists because conspiracy requires an 'agreement,' and a person cannot *negligently* agree to something—an agreement can only be reached with intent."); *Sonnenreich v. Philip Morris Inc.*, 929 F. Supp. 416, 419 (S.D. Fla. 1996) ("Logic and case law dictate that a conspiracy to commit negligence is a non

sequitur."); *Firestone Steel Prods. Co. v. Barajas*, 927 S.W.2d 608, 614 (Tex. 1996) ("Given the specific intent requirement, parties cannot engage in a civil conspiracy to be negligent.").[23]

CONCLUSION

For the foregoing reasons, the Tribes' complaints should be dismissed on the pleadings.

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Respectfully submitted,

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[23] Nor have the Tribes come close to pleading any type of agreement between the diverse group of Manufacturers and/or any other Defendants sufficient to state a claim for civil conspiracy. *See Summit* MTD § XIII.

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ADDENDUM A

Grounds For Dismissal

Muscogee Nation's Complaint

Claim[1]	**Grounds for Dismissal**
RICO: Marketing Enterprise (Count I)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No injury to business or property – Section II.C • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
RICO: Supply Chain Enterprise (Count II)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No injury to business or property – Section II.C • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Lanham Act (Count III)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • Not within the zone of interests – Section II.D • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B

[1] Counts VII, VIII, and IX are alleged against the "Diversion Defendants." The Manufacturers are not included within that group. *See* Muscogee 1AC ¶ 14.

Claim[1]	Grounds for Dismissal
Nuisance (Count IV)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No valid claim of public nuisance – Section III.A • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Negligence and Negligence Per Se (Count V)	• No proximate cause – Section I.A • No duty – Section I.B • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No negligence per se – Section II.F • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Unjust Enrichment (Count VI)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No valid claim of unjust enrichment – Section III.B • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Civil Conspiracy (Count X)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • Statute of limitations – Section V.B • No actionable underlying tort – Section V.C

Blackfeet Tribe's Complaint

Claim	Grounds for Dismissal
RICO: Marketing Enterprise (Count I)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No injury to business or property – Section II.C • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
RICO: Supply Chain Enterprise (Count II)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No injury to business or property – Section II.C • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Public Nuisance – Federal Common Law (Count III)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No cause of action exists – Section III.A.2 • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Public Nuisance – Montana Common Law (Count IV)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No cause of action exists – Section III.A.2 • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B

Claim	Grounds for Dismissal
Public Nuisance – Montana Statutory (Count V)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No valid claim of public nuisance – Section III.A.1 • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Negligence and Negligent Misrepresentation (Count VI)	• No proximate cause – Section I.A • No duty – Section I.B • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No negligence per se – Section II.F • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Common Law Fraud (Count VII)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B
Unjust Enrichment (Count VIII)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No valid claim of unjust enrichment – Section III.B • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B

Claim	Grounds for Dismissal
Civil Conspiracy (Count IX)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • Statute of limitations – Section V.B • No actionable underlying tort – Section V.C
Montana Consumer Protection Act (Count X)	• No proximate cause – Section I.A • Cannot recover healthcare costs – Section II.A • Cannot recover public services costs – Section II.B • No consumer injury – Section II.E • Preemption – Section IV • Failure to allege fraud with particularity – Section V.A • Statute of limitations – Section V.B

ADDENDUM B

Tribes' Misrepresentation Allegations

Muscogee Nation's Complaint

Defendant	Misrepresentation	Date	Complaint ¶
Purdue	Purdue issued marketing materials, starting in 1996, stating that "addiction to opioids legitimately used in the management of pain is very rare."	1996	106
	From 1996 to 2001, Purdue conducted over 40 pain management and speaker training sessions at resorts to recruit and train physicians, nurses, and pharmacists as speakers on its behalf. Purdue trained over 5,000 people at these all-expenses-paid events. The DEA has estimated that Purdue funded over 20,000 opioid pain-related programs between 1996 and July 2002 through direct sponsorship or financial grants	1996-2002	133
	Purdue sponsored training sessions in the late 1990s and early 2000s where opioid addiction was described as "exquisitely rare.	Late 1990s to early 2000s	110
	Between 2001 and 2010, Purdue's "In the Face of Pain" website similarly presented statements of Dr. Portenoy and other KOLs who were portrayed as independent experts.	2001-2010	129
	Purdue salesmen were instructed to tell doctors that opioids' addiction risk was "less than one percent."	2003	109
	Likewise, "Treatment Options: A Guide for People Living with Pain," a 2006 American Pain Foundation pamphlet financially supported by Purdue, claimed that addiction is rare and limited to certain extreme cases.	2006	105
	Purdue used the term "pseudoaddiction" in numerous other marketing materials, including one entitled "Responsible Opioid Prescribing – A Physician's Guide."	2007	117
	Guidelines edited and sponsored by Purdue and Endo and put out by Front Groups—namely "Treatment Options: A Guide for People Living with Pain" (2006) and "A	2006, 2011	121

	Policymaker's Guide to Understanding Pain & Its Management" (2011)—claim that: (a) some patients "need" a larger opioid dosage, regardless of the dose prescribed; (b) opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain; and (c) dosage escalations, even unlimited ones, are "sometimes necessary."		
	For instance, an October 2011 pamphlet entitled, "A Policymaker's Guide to Understanding Pain & Its Management," put out by a Front Group called the American Pain Foundation and "made possible by support from Purdue Pharma LP," asserted that "[l]ess than 1 percent of children treated with opioids become addicted" and that pain was generally "undertreated" due to "misconceptions about opioid addiction.	Oct. 2011	105
	Purdue published a physician education pamphlet in 2011 suggesting that drugseeking behavior could be a sign of "pseudoaddiction," which was described as "[drug-seeking behaviors] in patients who have pain that has not been effectively treated."	2011	117
	As recently as June 2015, Purdue's "In the Face of Pain" website was promoting the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, the patient should find another doctor who will.	2015	122
	Also in 2015, Purdue presented a paper on the Problems of Drug Dependence, challenging the correlation between opioid dosage and overdose.	2015	122
	And in 2016, Purdue's Dr. Haddox falsely claimed that evidence does not show that Purdue's opioids are being abused in large numbers	2016	122
Endo	Endo also represented that "[t]aking opioids for pain relief is not addiction" and that "[a]ddiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problem." In the same publication, Endo suggested that patients use the following test to determine whether they are addicted to opioids: "Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve pain and improve your function. You are not addicted."	2004	108

	Endo distributed a pamphlet in 2004, "Understanding Your Pain: Taking Oral Opioid Analgesics," which stated that patients "won't 'run out' of pain relief" so long as they increase dosages	2004	123
	Endo also sponsored a website from 2004 to 2007, painknowledge.com, which claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain."	2004-2007	123
	For example, Endo sponsored painknowledge.com and painaction.com, which claimed, as of 2009 and 2015, respectively, that "[p]eople who take opioids as prescribed usually do not become addicted" and that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them."	2009, 2015	107
	Guidelines edited and sponsored by Purdue and Endo and put out by Front Groups—namely "Treatment Options: A Guide for People Living with Pain" (2006) and "A Policymaker's Guide to Understanding Pain & Its Management" (2011)—claim that: (a) some patients "need" a larger opioid dosage, regardless of the dose prescribed; (b) opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain; and (c) dosage escalations, even unlimited ones, are "sometimes necessary."	2006, 2011	121
	Endo distributed a pamphlet, "Living with Someone with Chronic Pain," which stated that most healthcare providers agree that most people do not develop an addiction.		106
	Endo also published materials promoting "pseudoaddiction."		117
Front Groups/KOLs	[Dr. Portenoy] also regularly repeated—including in a 1986 paper published in the journal of the American Pain Society, a 1996 paper written on behalf of the American Pain Society and the American Academy of Pain, and numerous lectures—the unsubstantiated claim that the addiction risk posed by opioids was lower than one percent	1986, 1996	128
	These Front Groups published many of the misleading "guidelines" described above, based on content and funding provided by Marketing Manufacturer Defendants, including: (1) "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic	2006, 2009, 2011	131

	Noncancer Pain" (2009);52 (2) "A Policymaker's Guide to Understanding Pain & Its Management" (2011);53 and (3) "Treatment Options: A Guide for People Living with Pain" (2006).		
	In 2007, the American Pain Society repeated Marketing Manufacturer Defendants' misstatements that addiction was a "rare problem" for patients using opioids for chronic pain and that there was "no causal effect . . . between the marketing of [a particular opioid] and the abuse and diversion of the drug."	2007	131
	Similarly, "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," a February 2009 article funded by the American Pain Society, another Front Group, and written by several authors with financial ties to Marketing Manufacturer Defendants, promoted opioids as "safe and effective" for chronic pain treatment and indicated that the risk of addiction was manageable for all patients regardless of past drug abuse history.	Feb. 2009	105
	In 2010, [Dr. Portenoy] said on Good Morning America that "[a]ddiction, when treating pain, is distinctly uncommon" and that "most doctors can feel very assured that that person is not going to become addicted."	2010	128

Blackfeet Tribe's Complaint

Defendant	Misrepresentation	Date	Complaint ¶
Purdue	Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."	1995	271
	In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."	May 31, 1996	160
	In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."	1996	227
	Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos says 'In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*."	1998	157
	Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two was set out in Purdue's internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.	1999	273
	Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids	1999-2005	165-63
	Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain."	"early 2000s"	162
	Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours."	2000	270
	At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of	Aug. 28, 2001	161

	overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional.		
	The FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient. [REDACTED].	2001	168
	In 2001, Purdue revised the indication and warnings for OxyContin, but [REDACTED].	2001	170
	Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."	2003	240
	[REDACTED]	2003	227
	Purdue acting with Endo sponsored Overview of Management Options, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.	2003, 2007, 2010, and 2013	262
	Purdue posted an unbranded pamphlet entitled Clinical Issues in Opioid Prescribing on its unbranded website, PartnersAgainstPain.com, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain.	2005	213
	Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 Journal of Pain and 2006	2005	271

	Clinical Journal of Pain featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message.		
	Purdue and Cephalon sponsored the APF's Treatment Options: A Guide for People Living with Pain (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed."	2007	204
	Purdue and Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids have "no ceiling dose" and therefore are safer than NSAIDs.	2007	233
	The APF's Treatment Options: A Guide for People Living with Pain (2007), sponsored by Purdue and Cephalon, counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.	2007-2012	246
	Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled Managing Patient's Opioid Use: Balancing the Need and Risk. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."	2011	205
	Purdue sponsored a 2011 CME program titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."	2011	206
	Purdue's Pain Management Kit is another example of publication used by Purdue's sales force that endorses pseudoaddiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." Upon information and belief, the kit was in use from roughly 2011 through at least June 2016.	2011-2016	214
	Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.	2012	207

	A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.	2012	242
	Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.	2016	289
	Purdue sponsored the American Pain Foundation's ("APF") A Policymaker's Guide to Understanding Pain & Its Management, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.		233
	sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics		228
	Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."		241
	The APF's Treatment Options: A Guide for People Living with Pain, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdoses, when the figure is closer to 3,200.		256

Endo	Purdue acting with Endo sponsored Overview of Management Options, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.	2003, 2007, 2010, and 2013	262
	Endo paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, (i) recommended screening patients using tools like (a) the Opioid Risk Tool created by Dr. Webster and linked to Janssen or (b) the Screener and Opioid Assessment for Patients with Pain, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to by Endo-supported websites, as well.	2007	208
	Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") Responsible Opioid Prescribing (2007) written by Dr. Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction."	2007	212
	In April 2007, Endo sponsored an article aimed at prescribers, published in Pain Medicine News, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain." The article asserted: Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.	April 2007	260
	Endo also sponsored a NIPC CME program in 2009 titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudoaddiction and listed "[d]ifferentiation among states of physical	2009	216

	dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.		
	a 2009 patient education publication, Pain: Opioid Therapy, funded by Endo and posted on www.painknowledge.com, omitted addiction from the "common risks" of opioids	2009	180
	Further, a January 4, 2011 FDA Discipline Review letter made clear to Endo that "[t]he totality of these claims and presentations suggest that, as a result of its new formulation, Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. In addition these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's "INTAC" technology confers some form of abuse-deterrence properties when this has not been demonstrated by substantial evidence."	January 2011	295
	Similarly, since at least May of 2011, Endo has distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.	May 2011	243
	Endo knew by July 2011 that "some newer statistics around abuse and diversion are not favorable to our product."	July 2011	292
	Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers.	December 2011 - ~September 2012	300
	An Endo publication, Living with Someone with Chronic Pain, stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.	"until at least April 2012"	179
	The FDA expressed similar concerns in nearly identical language in a May 7, 2012 letter to Endo responding to a February 2, 2012, "request … for comments on a launch Draft Professional Detail Aid … for Opana ER." The	May 2012	296

	FDA's May 2012 letter also includes a full two pages of comments regarding "Omissions of material facts" that Endo left out of the promotional materials.		
	In its written materials, Endo marketed Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."	June 2012	308
	In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."	September 2012	309
	A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers.	January 2013	310
	Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant."	April 2013	310
	Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC") and its website www.painknowledge.com, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."		176
	Another Endo website, www.PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."		177
	A brochure available on www.painknowledge.com titled "Pain: Opioid Facts," Endo-sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted."		178
	A non-credit educational program sponsored by Endo, Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's		222

	opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids.		
	Endo sponsored a website, www.painknowledge.com, which claimed that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.		231
	Endo also published on its website a patient education pamphlet entitled Understanding Your Pain: Taking Oral Opioid Analgesics. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased . . . You won't 'run out' of pain relief."		232
	Endo's NIPC website www.painknowledge.com claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy.		247
	Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.		248
	Endo's NIPC website, www.painknowledge.com, which contained a flyer called "Pain: Opioid Therapy." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.		258
	the Endo-sponsored CME put on by NIPC, Persistent Pain in the Older Adult, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have "possibly less potential for abuse than in younger patients," and does not list overdose among the adverse effects.		259

	Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. Upon information and belief, based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe.		306
Janssen	Similarly, Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.	2007	244
	[REDACTED].	August 2008 – August 2009	182
	Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which states as "a fact" that "opioids may make it easier for people to live normally." This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"	2009	244
	Janssen sponsored Finding Relief: Pain Management for Older Adults (2009), that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids	2009	257
	Janssen sponsored, funded, and edited a website called Let's Talk Pain, which in 2009 stated "pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until at least May 2012.	2009-2012	218
	[REDACTED].	2012	234
	A Janssen unbranded website, PrescribeResponsibly.com, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."	current	183
	Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults, which, as seen below, described as "myth" the claim that opioids are addictive, and asserted	"until recently"	184

	as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Until recently, this guide was still available online.		
	Janssen also currently runs a website, Prescriberesponsibly.com, which claims that concerns about opioid addiction are "overestimated," and describes pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases."	Current	219
	[REDACTED].		186
	[REDACTED]		188
	Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."		238
	Janssen's Let's Talk Pain website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.		245
Cephalon	a 2003 Cephalon-sponsored CME presentation titled Pharmacologic Management of Breakthrough or Incident Pain, posted on Medscape in February 2003	Feb. 2003	191
	Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft	2007	190
	Purdue and Cephalon sponsored the APF's Treatment Options: A Guide for People Living with Pain (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed."	2007	204
	Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") Responsible Opioid Prescribing (2007) written by Dr.	2007	212

	Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction."		
	Purdue and Cephalon sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids have "no ceiling dose" and therefore are safer than NSAIDs.	2007	233
	The APF's Treatment Options: A Guide for People Living with Pain (2007), sponsored by Purdue and Cephalon, counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.	2007-2012	246
	[REDACTED].		192
	The APF's Treatment Options: A Guide for People Living with Pain, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdoses, when the figure is closer to 3,200.		256
Allergan	Through its "Learn More about customized pain control with Kadian," material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."		193
	Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.		194
	A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of		196, 313

	morphine sulfate for intravenous use by illicit users," and 2) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state."		
Mallinckrodt	Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled Defeat Chronic Pain Now! This book is still available online. The false claims and misrepresentations in this book include the following statements: [list]	2010-2012	198-99
	For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.	Aug. 27, 2012	314
	In a 2013 Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."	2013	200
	With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."	Mar. 7, 2014	315
	Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."	Current	249

LOCAL RULE 7.1(f) CERTIFICATION

I certify that these cases have been assigned to the "Tribal Track Cases" pursuant to CMO Six and that this Memorandum adheres to the page limitations set forth in the Court's July 26, 2018 Order Regarding Page Limitations, Dkt. 791, and L.R. 7.1(f).

Dated: August 31, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on August 31, 2018, a copy of the foregoing Memorandum of Law in Support of the Manufacturer Defendants' Joint Motion to Dismiss the Tribes' First Amended Complaints was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Dated: August 31, 2018

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